

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date October 25,1999

MEMORANDUM

SUBJECT: Tetrachlorvinphos (Chemical ID No. 083701/List A Reregistration Case No. 0321)

Revised Occupational and Residential Exposure and Risk Assessment for the Health

Effects Division RED. DP Barcode: D257557, Submission No. S564917.

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Pesticide Chemical Code: 083701

EPA MRID Nos.: 42622301, 44859401, 44859402, 44859403, 44859404, 44859405, 44859406,

44859407, 44859408, 44859409.

PHED: Yes, Version 1.1 (August 1998).

CONCLUSIONS

This occupational and residential exposure assessment contains many revisions and supercedes the previous chapters submitted for this chemical S. Hanley (6/1/99, D254823). Revisions reflect the submissions and HED reviews of residential exposure and postapplication studies completed by Hartz Mountain Corporation (Hartz). No changes were made to the occupational exposure assessment and no toxicological endpoints were changed from the 6/1/99 occupational and residential exposure and risk assessment document.

Use Patterns supported through reregistration include oral larvicide uses for livestock, direct dermal treatment of beef and dairy cattle (including lactating cattle), horses, poultry and swine; and livestock premise treatments. Homeowner use products allow application to pets and their bedding to control fleas and ticks. Residential handler and postapplication exposures will be aggregated in the residential scenarios.

Summary/Conclusions

This exposure assessment evaluated handler risks due to use and postapplication exposure to tetrachlorvinphos products. HED is concerned with handler risks estimated for residential exposures. In both short- and intermediate-term non-cancer exposure scenarios and for carcinogenic risk, the Agency's level of concern is exceeded. The specific exposure scenarios include applying insecticidal dip or powder products and contact with treated pets that involves hand-to-mouth activity (toddlers only).

Eight exposure studies were submitted to assess residential handler and postapplication exposure to tetrachlorvinphos products. These studies had low replicate numbers, invalidated methods, and little quality control/analysis. The studies were reviewed, and the data were used to assess the <u>range</u> of residential exposures.

Label changes were submitted by the Registrant in a risk assessment document that modified application rates and more clearly defined amount of product per application. Marketing data submitted for residential product use was the basis for residential lifetime exposure and cancer risk. The market data were unclear and non-specific, however, they closely mirrored the data used in the previous assessment collected from the National Home and Garden Pesticide Use Survey. Estimates of carcinogenic risk are considered to be conservative, based on assumptions made regarding the number of applications per year, the amount applied and the number of years of pet ownership.

Adult dermal postapplication exposure yielded MOEs above 100 (i.e., below the Agency's level of concern); assessment of a toddler hugging a treated animal resulted in MOEs of 93 to 1600. The MOEs for toddler hand-to-mouth exposure were found to be <u>under</u> 100 for maximum transfer rates for powder, aerosol and pump spray uses (MOEs 74 to 99). The combined results for handler and postapplication carcinogenic risk ranged from 2.0 x 10⁻⁷ to 3.7 x 10⁻⁶ for the average transfer rate and 2.3 x 10⁻⁷ and 3.8 x 10⁻⁶ for the maximum transfer rate (see Table 13).

Use of a product on pet or in pet areas (i.e., handling and postapplication exposure) was added to exposure from application of a pet collar to estimate combined risk. This was described

as the most likely combination of products by Hartz. The calculations resulted in a carcinogenic risk range of 1 x 10^{-7} to 3.7 x 10^{-6} for average transfer rates, and 1.4 x 10^{-7} to 3.8 x 10^{-6} for maximum transfer rates.

1 Occupational and Residential Exposure/Risk Assessment

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. Tetrachlorvinphos toxicological endpoints were selected for short- and intermediate-term exposures; no chronic exposure scenarios are thought to exist for tetrachlorvinphos, based on currently available information. In addition, tetrachlorvinphos is classified as a Group C possible human carcinogen and it has a Q_1 * of $1.83 \times 10^{-3} (mg/kg/day)^{-1}$. Based on the potential for exposure, risk assessments are required for occupational and residential handlers and for residential postapplication scenarios.

Toxicologic endpoints selected by Hazard Identification Assessment Review Committee are as follows for tetrachlorvinphos. The toxicologic endpoints will be used in this assessment to evaluate tetrachlorvinphos exposure risks to workers and residential handlers.

Table 1: Toxicological Endpoints Selected.

Exposure Scenario	NOAEL (mg/kg/day)	Study	Endpoint (LOAEL, mg/kg/day)	Dermal Absorption Factor	Uncertainty Factors
Short- and Intermediate- term Dermal	4.23	Subchronic Neurotoxicity	Plasma/RBC ChE Inhibition at 13 weeks	9.57 %	100 X (conventional) 1X (FQPA)
Short- and Intermediate- term Inhalation		Study-Rat	(LOAEL = 43.2 mg/kg/day)	100 %	

From Hazard Assessment of Organophosphates, July 7 1998.

a. Use Pattern/Available Products Summary for Exposure Assessments

Tetrachlorvinphos ((Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate) is an insecticide federally registered for use as an oral larvicide for livestock and for direct treatment of beef cattle, dairy cattle (including lactating animals), horses, poultry, swine, livestock premises, and pets.

The formulations registered for use on animals include wettable powder, treated articles (ear tags), dust, ready-to-use solution and emulsifiable concentrates. Other than treated articles, these formulations may be applied directly as a spray, as a backrubber solution, in a dust-bag, and as a dust. Tetrachlorvinphos granules or pellets also can be used for feed-through purposes or supplied in a mineral block supplement to control fecal flies (oral larvicide). The formulations registered for animal premise treatments include the wettable powder, dust, and emulsifiable concentrate, which may be applied as paint on and/or residual spray. [Source: Office of Pesticide Programs – Reference Files System(REFS)].

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity.

The following table summarizes all active Section 3 labels; their formulation, percent active ingredient and EPA registration number. The distribution of these labels is as follows: 2 technical products, 6 wettable powders, 16 dusts, 55 feed through (granules), 5 emulsifiable concentrates, 3 pressurized liquids, 6 ready to use sprays and 9 impregnated materials. There are no SLN labels active for this product according to the REFS review.

Table 2: Active EPA Registration Numbers for Tetrachlorvinphos Products.

Form	Percent active ingredient	EPA Registration Number
Technical	98.7	2596-131; 4691-149
Wettable powder	50; 75	70-191; 4691-128,-129,-139; 28293-76; 34704-432; 47000-68
Dust 3; 1		70-192,-224; 299-188; 2393-393; 2596-78,-79; 4691-131,-138; 19713-340; 28293-13; 34704-266,-276,-307; 47000-66,-67; 67517-40
Feed through (Granules) 2.5; 1.5; 7.8; 97.3; 1; 0.7; 0.3; 97; 0.2; 1.2; 0.35		270-164,-165; 602-268; 1304-63,-64,-66,-68; 1352-60;1990-386,-387; 2011-5,-6,-7,-10; 4691-133,-134,-135; 4987-5; 6482-8; 6552-12,-13,-14,-17; 7138-12; 7455-23; 7627-21,-22,-26; 7698-7; 9078-6,-12; 9374-8,-9; 12714-3; 20552-2; 37774-1; 38092-3; 38110-4,-7,-8,-9; 40833-4,-5,-6,-8,-11,-12; 41200-2; 43757-1; 44666-1; 48390-1; 55392-3; 59345-1; 65901-1; 67517-26
Emulsifiable Concentrate	3; 24; 23;	2596-119; 4691-132,-136,-137; 67517-33
Pressurized Aerosol	1.1	2596-122,-123,-141
Ready to use Spray	1.1; 1; 2	2596-125,-126,-136,-140; 28293-27,-28
Impregnated Materials	14.55; 13.7	2596-49,-50,-62,-63,-83,-84,-139; 4691-150,-151;

Tetrachlorvinphos is an organophosphate insecticide that works as a contact or systemic poison and is used to control pests on animals or in and around animal quarters. The use sites are as follows:

Terrestrial Feed Crop: Cattle feedlots.

<u>Indoor food:</u> Agricultural/Farm Structures/Buildings and Equipment, Beef/Range/Feeder Cattle, Cattle Feedlots, Dairy Cattle (Lactating or Unspecified), Hog/Pig/Swine (Meat), Livestock, Poultry (Meat). <u>Indoor Residential:</u> Cats (Adults/Kittens), Dogs/Canines (Adults/Puppies), Household/Domestic Dwellings Indoor Premises.

Indoor Nonfood:, Mink (Fur Animal), Sheep, Specialized Animals.

The target pests are: fleas, ticks, lice, mites, spiders, wasps, cattle grubs, and flies- both larvae and adults.

Tetrachlorvinphos has a number of residential and occupational uses. For clarity, these have been separated into occupational and homeowner/residential uses.

2 Occupational Handler (mixer/loader/applicator) Exposure/Risk Assessment

Tetrachlorvinphos is applied using handheld equipment or as a feed through or via rub on application. Application rates include either specific maximum rates for cattle/swine and other farm animal premise treatments. Other labels indicate delivery through a "permit free access" (e.g., free-choice mineral blocks, feed- through or rub-on products).

The Agency has determined that there is potential occupational exposure to mixers, loaders and applicators during mixing/loading of liquids and wettable powders, and from applying aerosol spray, dusts, granules/pellets, using high pressure or low pressure handwands, and treated articles. The current exposure assessment is based on the product labels that contain representative uses, rates of active ingredient application and application scenarios. These labels are: EPA Registration Numbers: 4691-132, 4691-133, 4691-128 (previously 56493-29, 56493-34, 56493-13, which were transferred).

Based on the supported use patterns the following major exposure scenarios were identified for tetrachlorvinphos:

- (I) mixing/loading liquids for spray applications, (II) mixing/loading granules for feed-through,
- (IIIa) mixing/loading wettable powder for high pressure handward application (data from MRID 426223-01),
- (IIIb) mixing/loading wettable powder for high pressure handward application (data from PHED 1.1),
- (IV) applying tetrachlorvinphos using a product in an aerosol can, (V) animal dusters,
- (VI) applying pellets,
- (VIIa) applying tetrachlorvinphos using high pressure handward (data from MRID 426223-01),
- (VIIb) applying tetrachlorvinghos using high pressure handwand (data from PHED 1.1),
- (VIIc) applying tetrachlorvinphos using high pressure handwand, double layer clothes, gloves and dust/mist respirator,
- (VIII) mixing, loading and applying tetrachlorvinphos using a low pressure handwand, and
- (IX) mixing/loading/applying tetrachlorvinphos using a backpack sprayer.

a. Data Sources

Mixer/loader/applicator (M/L/A) exposure studies were required in the Guidance for the Reregistration of Pesticide Products Containing Tetrachlorvinphos (October 1988). Data from one indoor site and one outdoor site were required.

Chemical-specific M/L/A data for Rabon® 50 WP were generated using high pressure handwards for the interior of poultry houses (MRID 426223-01). This study is not included in PHED, but has been used in this risk assessment. The data from this study have been accepted for use in this chapter (See Memo K. Boyle dated 6/18/98).

MRID 426223-01: Dermal and inhalation levels were quantified for workers applying tetrachlorvinphos product Rabon® 50 WP in a poultry house using high power handwand sprayers. The study monitored 16 replicates (e.g., four workers and four replicates) of mixing/loading and 16 replicates of application for inhalation and dermal exposures. The sprayers applied Rabon® 50 WP with handheld wand-type sprayer via a crack and crevice type application to floors, walls and ceilings of poultry houses in two different locations in Delaware. Each mixing/loading replicate consisted of mixing 20 lb ai in 225 gallons of water in a 2000 gallon tank. Each applicator sprayed 8.9 to 32 lb ai in 102 to 362 gallons of water per replicate. MRIDs 442027-01 and 442027-02 contain supporting data, such as method validation and storage stability data.

Dermal exposure was monitored using cotton whole body dosimeters (i.e., union suits) worn under polyester/cotton coveralls. Head and neck exposures were monitored with patches (cotton glove fabric in aluminum foil frames) approximately 50-60 cm² each. Workers wore neoprene chemical-resistant gloves. Hand exposure was monitored using hand rinse solutions. SKC Chromasorb 106 air sampling tubes were used to monitor inhalation exposure. QA/QC procedures included field recoveries, method validation and concurrent laboratory recoveries were acceptable.

Chemical-specific data for assessing human exposures during pesticide handling activities were submitted to the Agency in support of the reregistration of tetrachlorvinphos. It is the policy of HED to combine submitted chemical-specific data with those from the Pesticide Handlers Exposure Database (PHED) Version 1.1 (August 1998) to assess handler exposures for regulatory actions because individual studies may not encompass the variety of agricultural equipment in use throughout the country and the inter-variability of exposures among handlers.

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates)

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g.,

chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table 5. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.^{1,2}

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include administrative controls, the use of personal protective equipment or PPE, and the use of engineering controls. Occupational handler exposure assessments are completed by HED using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure (MOE) or cancer risk. [Note: Administrative controls available generally involve altering application rates for handler exposure scenarios. These are typically not utilized for completing handler exposure assessments because of the negotiation requirements with registrants.] The baseline clothing/PPE ensemble for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical-resistant gloves, and no respirator. The first level of mitigation generally applied is PPE. As reflected in the calculations included herein, PPE involves the use of an additional layer of clothing, chemical-resistant gloves and a dust/mist respirator. The next level of mitigation considered in the risk assessment process is the use of appropriate engineering controls which, by design, attempt to eliminate the possibility of human exposure. Examples of commonly used engineering controls include closed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets.

b. Occupational Exposures and Risks (non-cancer)

HED's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. Tables 4, 4A and 4B present daily dermal and inhalation exposure values for baseline and additional PPE clothing scenarios. Table 4 contains the daily exposure unit values with baseline represented as the unit exposure with long-sleeved shirt, long pants no respirator and no gloves. The additional PPE unit exposures represent daily exposure while wearing long-sleeved shirt, long pants, chemical resistant gloves and a dust/mist respirator.

Where noted, additional PPE of a second layer of clothing consists of long-sleeved shirt, long pants has been added. The assumptions include application rates according to listed label uses, specific application methods and a value for the amount of tetrachlorvinphos that can be used in a single working day based on the job function (e.g., acres per day).

In Table 4A, the daily dermal exposure, daily dose and risks to handlers was calculated for baseline scenarios (i.e., no additional PPE) as described below. The first step is to calculate daily dermal exposure using the following formula:

Daily Dermal Exposure (mg ai/day) = Unit Exposure (mg ai/lb ai) * Application Rate (lb ai/A) *Daily Acres Treated (A/day).

Where:

Daily Dermal Exposure = Amount deposited on the surface of the skin that is available for dermal absorption, also referred to as potential dose (mg ai/day);

Unit Exposure = Normalizes exposure value derived from May 1997 PHED Surrogate Exposure Table or December 1997 SOPs for Residential Exposure Assessment Surrogate Exposure Table for homeowner applications, for Scenarios IIIa, VII use chemical-specific handler data from MRID 426223-01 (mg ai/pound ai applied):

Application Rate = Normalized application rate based on a logical unit treatment such as acres or on a per animal basis, a maximum value is generally used (lb ai/A or lb ai/animal); and

Daily Acres Treated = Normalized application area based on a logical unit treatment such as acres or numbers of animals (A/day or animals/day).

Daily dermal dose was then calculated by normalizing the daily dermal exposure value by body weight and accounting for dermal absorption (i.e., a biologically available dose resulting from dermal exposure). For adult handlers using tetrachlorvinphos, a body weight of 70 kg was used for all exposure scenarios because the toxic effect (cholinesterase inhibition) is not sexspecific. Additionally, a dermal absorption factor of 9.57 percent (from MRID 421115-01) was used for all calculations. Daily dermal dose was calculated using the following formula:

Daily Dermal Dose
$$\left(\frac{\text{mg ai}}{\text{kg-day}}\right)$$
 = Daily Dermal Exposure $\left(\frac{mg \text{ ai}}{day}\right) * \left(\frac{\text{Dermal Absorption Factor}(\%/100)}{\text{Body Weight (kg)}}\right)$

The next step was to calculate the daily inhalation exposure for handlers. The process used is similar to that used to calculate the daily dermal dose to handlers. Daily inhalation exposure levels were presented as (µg/lb ai) values in the PHED Surrogate Exposure Table of August 1998 (i.e., these values are based on an inhalation rate of 29 liters/minute and an 8 hour exposure interval). Once the unit exposure value is presented in this form and converted to (mg/lb ai), the calculations essentially mirror those presented above for the dermal route using a value of 100 percent absorption (i.e., a daily inhalation dose is calculated in mg/kg/day).

The handler exposure assessment does not include any dietary or drinking water inputs.

Finally, the calculations of daily dermal dose and daily inhalation dose received by handlers were then combined to assess the total risk to handlers for each exposure scenario. Short- and Intermediate-term total MOEs were calculated using the NOAEL of 4.23 mg/kg/day (Note: See the Swartz Memo dated November 2, 1998; Addendum to HED RED) and the formula below:

$$MOE = \frac{NOEL\left(\frac{mg}{kg/day}\right)}{TotalDailyDose\left(\frac{mg}{kg/day}\right)}$$

A margin of exposure (MOE) uncertainty factor of 100 is considered to be protective for both the short- and intermediate-term exposures to tetrachlorvinphos.

Table 4B represents calculated dermal and inhalation exposure and dose with additional PPE protection. The PPE are added levels to achieve MOEs that are below the level of concern (MOE > 100). Most scenarios were found to be acceptable with single layer clothes (i.e., long-sleeved shirt, long-pants), chemical resistant gloves and a dust/mist respirator. The high pressure handwand (VIIc) required double layer of clothes, chemical resistant gloves, and a dust/mist respirator. The backpack scenario (IXb) is not within Agency's level of concern for relevant risks [MOE \geq 100 (MOE_{IXb} = 3.8 and 6.4 respectively)] with additional PPE including double layer clothes, chemical resistant gloves and a dust/mist respirator.

Table 5 summarizes the caveats and parameters specific to the data used for each exposure scenario. These caveats include descriptions of the source of the data and an assessment of the overall quality of the data. Generally, the assessment of data quality is based on the number of observations and the available quality control data. Quality control data are assessed based on grading criteria established by the PHED task force and the reliability of any assumptions excerpted from the *SOPs for Residential Exposure Assessment (September 1997)* when it is appropriate. Additionally, it should be noted that all calculations were completed based on current HED policies pertaining to the completion of occupational and residential exposure/risk assessments (e.g., rounding, exposure factors, and acceptable data sources).

c. Occupational Handler Carcinogenic Risk Assessment

Since tetrachlorvinphos is a suspected human carcinogen it is assumed that any amount of exposure will lead to some degree of carcinogenic risk. It is also assumed that risk is directly and linearly proportional to exposure, regardless of the dosing schedule. This approach utilizes a slope factor known as the cancer potency factor, Q_1^* , calculated by the HED Cancer Peer Review Committee. The Q_1^* value was established using Weibull 83 time-to-tumor model, resulting in a $Q_1^* = 1.83 \times 10^{-3}$. Table 6 uses the Q_1^* and amortizes the Total Daily Absorbed Dose from Table 4A to calculate the carcinogenic risk.

The first step to calculate the carcinogenic risk is to amortize the Total Daily Absorbed Dose from Table 4A over the working lifetime of occupational handlers based on use patterns, this results in the Lifetime Average Daily Dose (LADD). As identified in Table 5, product labels recommend weekly use before flies appear until cold weather restricts their activity. This results in a 6 month use period or a full year use period depending on climate. Finally, a 35 year career of a 70 year lifespan covers the number of years of application. The resulting equation for LADD follows:

$$LADD\left(\frac{mg}{kg/day}\right) = Total \ Absorbed \ Daily \ Dose\left(\frac{mg}{kg/day}\right) * \frac{\text{Annual Treatment Days}}{365 \ \text{Days/year}} \left(\frac{35 \ \text{years working}}{70 \ \text{year lifespan}}\right)$$

The Carcinogenic Risk is calculated as follows:

Carcinogenic Risk = LADD
$$(mg/kg/day) * Q_1^*(mg/kg/day)^{-1}$$
.
Where $Q_1^* = 1.83 \times 10^3$.

LADD for occupational exposure with additional PPE (Table 7) is calculated using the same equations as Table 6 and the Total Absorbed Daily Dose from Table 4B. The LADD with additional PPE multiplied by the Q_1^* results in a carcinogenic risk range of 2.4 x 10^{-7} (low pressure handwand, VIII) to 1.5 x 10^{-4} [(backpack, single layer clothes, gloves and a dust/mist respirator, IXa) Table 7].

Table 7A considers the same PPE and Total Absorbed Daily Dose with a 3 days per year application during a 35 year career of a 70 year lifespan. This is considered a more typical use and results in a carcinogenic risk between 2.7×10^{-8} (low pressure handwand) to 8.6×10^{-6} (backpack, single layer clothes, gloves and a dust/mist respirator, IXa).

<u>d.</u> Residential Handler/Applicator Exposure/Risk (non-cancer)

Products containing tetrachlorvinphos are registered for use on dogs and cats for control of ticks and fleas. A search of the Agency's REFs database, conducted on 10/7/98, identified 102 products containing tetrachlorvinphos. End-use products with residential uses are marketed in the following formulations: impregnated collars, powders/dusts, emulsifiable concentrates, aerosol spray (pressurized liquids), ready-to-use pump sprays and wettable powders. In July 1999 Hartz Mountain Corporation submitted residential handler and postapplication studies. These studies are reviewed herein for use in residential exposure assessments. The draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 1997), as well as the available data (aerosol spray) in PHED, were also used for estimating exposure.

i. data sources

MRID 44859402 and MRID 44859405: Glass, R. June, 1999; Hartz Mountain In Use Risk Assessment of a Flea Collar, Dermal Exposure.

Two studies were conducted to determine residential handler exposure to the tetrachlorvinphos in a **flea collar** during application. Both studies involved the handler snapping or stretching the collar to "activate"; however, in one of the studies the handler also wiped a gloved hand down the length of the collar before applying to the dog (referred to below as "wipe study"). The glove was used to collect the amount of tetrachlorvinphos available for dermal exposure. According to the investigator, the wiping action represented an inexperienced collar handler applying the product.

Average and maximum transfer rates for the "non-wipe" collar study were 0.22 and 0.28 percent, respectively. The "wipe" study average and maximum transfer rates were 0.30 and 0.42 percent, respectively. The "wipe" study average and maximum transfer rate results were chosen to calculate the range of residential exposure during impregnated collar application. The transfer rate of tetrachlorvinphos was slightly higher than the "non-wipe" study and represents a typical residential scenario. No characterization of cotton glove to skin similarities was given and no hand rinses were carried out to determine penetration of gloves. Glove samples were only rinsed once with 50 ml of extractant in a 60 ml jar. Low replicate numbers in both studies and different protocol methods of application did not allow combining of the studies results. The maximum and average exposure rates from the replicates will be used to characterize a range of exposures for this scenario.

MRID 44859403 and MRID 44859404: Glass, R., June,1999; Hartz Mountain In Use Risk Assessment of a Simulated Dip, Dermal Exposure.

Two studies were conducted to determine residential handler exposure to water during **simulated dip application** to a dog. In one study, the handler placed the dog in 5 gallons of water in a tub and used a cup to thoroughly soak the animal. In the other study, the handler used one gallon of water and a sponge-on technique to wet the animal.

Both of these studies applied "mass balance" to determine the amount of water a residential handler was exposed to. Each article of clothing, towels, tub, water and animal were weighed immediately prior to and after the dipping procedure. The differences in the weights of the articles (or dog) represented the amount of end product on that object or dog. Unaccounted for grams of water, "missing water," was applied to the dog exposure. This did not account for handler exposure to the hand and incidental dermal exposure to the forearms and head.

HED did not review these protocols before the studies were initiated. Due to the application of water instead of end product, low numbers of replicates, differing fur lengths, lack of characterization of dermal exposure, usage of 5 gallons when end use concentrate packaging would result in 4 gallon use, and lack of scale calibration and characterization these studies were used as <u>comparison data only</u>. To estimate dermal exposure, the Agency used an exposure model known as the Exposure Fate Assessment Screening Tool.

Exposure Fate Assessment Screening Tool

The Office of Toxic Substances' Exposure Fate Assessment Screening Tool (E-FAST) was used to evaluate dermal exposure to tetrachlorvinphos during application of the dip. E-FAST was developed as a screening level tool to support the Environmental Protection Agency (EPA) assessments of the potential exposures to new chemicals which are submitted to EPA under Section 5 of the Toxic Substances Control Act (TSCA). It should be noted that screening level tools are rarely, if at all, used as the sole justification for regulatory decision making at EPA. Additional data and more rigorous methods are

used to improve the estimates of exposures and risks for such decisions.

The exposure scenarios in E-FAST contain default exposure parameter values which allow the exposures to be estimated with minimal data entry. It should be noted that because E-FAST incorporates either a combination of upper percentile and mean exposure parametric values or all upper percentile parametric values as defaults, the potential dose rate estimates are considered "high end" estimates.

The Consumer Exposure module of E-FAST has undergone external peer review. EPA intends to have the module undergo external peer review in the near future.

Consumer product values entered into E-FAST are molecular weight, weight fraction in consumer products (concentration), and measured or estimated vapor pressure of the chemical (torr). In addition to the required information listed above, E-FAST also requires other exposure parameter information concerning body weights, intake rates, etc. Default values for each of these parameters are provided in the model for three population groups (adults, children, and infants) and two exposure types (acute and chronic), where appropriate. Most of these default values are conservative in nature and are the "recommended" values in EPA's *Exposure Factors Handbook* (U.S. EPA, 1997)³. For the tetrachlorvinphos hand exposure from dipping a dog, only adult body weights were considered.

The film thickness approach assumes that exposure occurs from a thin layer of the consumer product on a defined skin surface area to determine potential exposure. The film thickness resulting from dipping a dog in tetrachlorvinphos solution was derived from the initial immersion film thickness of water on the hands after immersion into laundry water, 0.897 mg/kg/day. The dilution fraction was estimated from the dilution of ½ cup of detergent (product) per use in a medium load (approximately 4-7 gallons)⁴. From this tool, dermal exposure to hands from application of a dip was calculated to be 63 mg, which will be added to the study data to account for hand exposure.

A series of assumptions and exposure factors served as the basis for completing homeowner handler risk assessments. Each assumption is detailed below:

EPA's Exposure Factors Handbook (1997)

- Dermal exposure from hugging a treated animal was based on mean surface area of front surface of forearms, lower legs, face and hands, 1150 cm² for a 3-4 year-old,
- Exposure factors used by the Agency in this assessment include a method for calculating the application rate to pet animals based on a relationship between skin surface area and weight [submitted studies (average and maximum application rates) and EPA Wildlife Exposure Factors Handbook (surface area of animal) as discussed in SOPs for Residential Exposure Assessments];

• Based on the EPA's Exposure Factor's handbook, toddler total skin area per hand-to-mouth event is 89 cm²:

Residential SOPs

- The average body weight of an adult used in all assessments is 70 kg. The NOAEL used for the short- and intermediate-term assessments (4.23 mg/kg/day) is based on a dose-response assessment (MRID 421115-01). For toddler assessments, 15 kg weight was used as directed by SOPs for Residential Exposure Assessment.
- Ten percent of the ai applied to the pet is available for dermal exposure during dipping and dusting (powder) treatments.
- Hand-to-mouth frequency was 1.56 times per hour, 2 hour set exposure per day,
- Average pet surface area is 6000 cm² which is the average surface area of a medium size dog (30 lb.).
- Infinite replenishment of residues for dermal and hand-to-mouth exposure scenarios in a residential setting.

Submitted Studies

- For direct animal treatments, a range of application rates was used from the submitted studies (i.e., average and maximum application rates).
- Fur-to-hand ai transfer is based on average and maximum dislodged residues demonstrated in studies;
- 50 percent efficiency of removal by saliva, from Registrant's use in risk assessment of 20% to account for solubility, which was based on literature study on a less soluble chemical; therefore the percentage increased from 20 to 50 percent for tetrachlorvinphos.

Exposure Fate Assessment Tool

• The dermal exposure value for the dip scenario accounted for immersion of both hands in liquid solution. This is considered reasonable since this application would involve both hands for application to and restraint of the treated animal and multiple hand-wettings to thoroughly treat animal.

Individual scenarios with their associated assumptions were developed for the residential use of collars, dips, powders and spray. Table 8 contains the scenarios and Table 9 contains the scenario descriptions, caveats and sources for the values. All scenarios are assessed at 2

application rates to represent average and maximum application rates demonstrated in the submitted studies and according to label directions. The collar scenarios were not divided due to the nature of the impregnated article treatment. These scenarios are described below:

Exposure Scenarios

- Dip scenarios are for 3 percent active ingredient concentrate solutions diluted 2 ounces to yield 1 gallon or 8 ounces to yield 4 gallons, depending on size of pet. (EPA Reg. No.: 2596 -119, 4691-139,28293-76).
- Use of average and maximum application for powder, spray and aerosol applications, as determined from studies (MRIDs:44859406, 44859407, 44859408, 44859409: EPA Reg. No.:56493-44; 2596-87,-89).
- Labels of impregnated collars state efficacy of 3-7 months, therefore, 2 collars/year was used in calculation; ai contained is 14.55 percent. (EPA Reg No.:2596-49,-50,-62,-63,-83,-84)

Baseline Dermal Unit Exposure

 Dermal unit exposures from product handling/application flea collar from study MRID 44859405 and dip studies plus hand exposure calculated with E-FAST; powder-according to the draft Residential SOPs (12/97); aerosol and pump spray unit exposure come from PHED V1.1.

Baseline Inhalation Unit Exposure

For dips, due to the low vapor pressure and conservative assumptions on which the dermal assessment is based (i.e., highest application rate and maximum area treated) inhalation exposure is considered minimal compared to the dermal exposure. For aerosol and pump sprays the PHED V1.1 data was used, an inhalation value is available for calculations.

Application Rates

Average and maximum application rates (per label directions/study results) were used except for a fixed ai product (e.g., flea collars).

Daily Treated

• Residential SOPs state one animal application per treatment.

Table 8 contains the calculations for residential handler scenario daily dermal and daily inhalation exposure, daily absorbed dermal and inhalation doses and the total daily absorbed dose. The total daily absorbed dose is compared to the short- and intermediate-term NOAEL of 4.23 mg/kg/day. Acceptable MOEs of >100 were obtained in collars, aerosol and pump sprays. The remainder of scenarios had MOEs between 4 and 49 [(1)Dip Res. SOPs and (2)Dip study plus E-

FAST and (5) powder Res. SOPs]. Mitigation of exposure by additional PPE is not considered to be practical in residential exposure scenarios. The equations used in Table 8 are as follows:

Daily Dermal Exposure (mg/day) = Baseline Dermal Exposure(% of ai applied, or mg/lb ai) * Application Rate(mg ai)* Daily Treated (animal/day)

Daily Inhalation Exposure (mg/day) Sprays = Baseline Unit Exposure (μ g/lb ai) * Application Rate (g ai) *Daily Treated (animal/day).

Daily Absorbed Dermal Dose = Daily Dermal Exposure * Dermal Absorption Rate/100percent ÷ Body Weight

Daily Absorbed Inhalation Dose = Daily Inhalation Exposure * 100 percent/100 Absorption \div Body Weight

Total Daily Absorbed Dose = Daily Absorbed Dermal Dose + Daily Absorbed Inhalation Dose

Short-/Intermediate-term MOE = NOAEL/ Total Daily Absorbed Dose

e. Residential Applicator/Handler-Carcinogenic Risk

Table 10 is a summary of the carcinogenic risk assessment for each residential scenario based on the Absorbed Daily Dose obtained in Table 8 and the tetrachlorvinphos Q_1^* of 1.83 x10⁻³ (mg/kg/day)⁻¹. PPE mitigation is not considered feasible in the residential use or postapplication exposures. The amortization for pet product use is described in the table, assuming one pet per household. Based on Hartz market data, typical use of flea and tick treatment products (unspecified) was estimated as follows:1 to 2 dips performed per year, 10 treatments per year for aerosol and pump spray, or 8 powder treatments.

Hartz submitted market data within the risk assessment (MRID 44859401). The market data implied consumers purchased 2 aerosol, powder and collar products per year. One dip product was the other noted trend. From the submitted information exact purchases of tetrachlorvinphos-specific products was unclear. The huge market selection for pet insecticidal treatments makes it unlikely that a tetrachlorvinphos treatments were purchased solely or more than once per year, with the possible exception of collars. Without clarification, the Agency used the submitted market data and assessed the lifetime average daily postapplication dose to aerosols, pump sprays and powders based on the use of 2 packages per year(i.e., between 8 and 10 treatments per year). Dip products were assessed for one and two uses per year and collars for 2 placements per year. See Table 10 for calculations.

Considering the various lifespans of pets and a possible succession of pets, 50 years of pet ownership during a 70 year life span is considered a conservative estimate. Values calculated for residential carcinogenic risk for application a tetrachlorvinphos product ranged from 6 x 10^{-9} to 7.1×10^{-6} . Use of the Residential SOPs for large dog dip and application of powder resulted in the residential handler risk exceeding 1×10^{-6} , the Agency's level of concern for carcinogenic risk. Note: use of the study data from simulated dip plus E-FAST hand exposure resulted in

carcinogenic risks within 10⁻⁷ as did study data without addition of hand exposure.

3 Postapplication Exposure/Risk Assessment

<u>a.</u> Occupational Post-Application Exposure/Risk (non-cancer)

Since none of the registered uses of tetrachlorvinphos are within the scope of the Worker Protection Standard for Agricultural Pesticides, restricted-entry intervals (REIs) are not required on the labels of products containing tetrachlorvinphos. Tetrachlorvinphos can be used as a feed-through. Given the mechanized systems for feed delivery in most feed-lots and the nature of manure removal, HED concludes that post-application exposure is minimal. (Note that the highest cancer risk estimate for mixing liquid or granular tetrachlorvinphos in the feed is 3.9 x 10⁻⁶).

The Agency has considered the potential post-application exposure arising from reentering indoor premises, such as poultry houses. Given the nature of activities performed in a poultry house, such as visually checking the condition of the caged birds, as well as feeding, and watering, contact with treated surfaces should be minimal. Therefore, the potential for dermal post-application exposure is assumed to be minimal. Since the vapor pressure of tetrachlorvinphos is 2.6 x 10⁻⁷ mm Hg at 25° C, HED concludes that post-application inhalation exposure is also minimal within treated poultry houses or other treated agricultural facilities.

Based on the use patterns for tetrachlorvinphos the potential for post-application exposure is considered to be minimal, and post-application exposure data are not required.

b. Residential Exposure/Risk Postapplication (non-cancer)

Hartz submitted four postapplication studies to quantify dislodgeable fur residue on pets treated with tetrachlorvinphos powders, dips, aerosol and pump sprays. Review of these studies follows:

MRID No. 44859406; 44859407; 44859408; 44859409: Glass, R:Hartz Mountain In Use Risk Assessment of an Insecticide. Total Dislodgeable Fraction of Active Ingredient from Treated Dogs

Four postapplication studies were conducted to quantify dislodgeable fur residue and gloved hand stroke exposure to tetrachlorvinphos from use of pump spray, aerosol spray, dip and powder. Hartz submitted label changes for the products mentioned, defining the application rate for use by residential handlers according to pet size.

The studies were conducted to obtain the dislodgeable fur residues and transfer rates of tetrachlorvinphos in the specific formulations. Baseline samples of fur and gloves were collected prior to treatment, and postapplication samples were collected at day after treatment (DAT) 0 (i.e., 4 hours after treatment), and at DATs 1,3, 7, 14, and 28. Each study included only 4 replicates (4 dogs), the maximum and average application rates will be used to characterize the range for product application and postapplication exposures. Average and maximum transfer rates obtained from the first sampling period DAT 0 were

be used to assess short- and intermediate-term residential postapplication exposure of adults and children to treated pets.

Table 3: Results of Postapplication Studies:

Study (MRID #)	Application Rate-mg		Transfer Rate-%		
	Average	Maximum	Average	Maximum	
Pump Spray (44859406)	380	400	4.7	6.9	
Aerosol Spray (44859407)	450	600	2.9	6.2	
Dip (44895408)	1800	1800	0.12	0.19	
Powder (44895409)	1500	1600	1.6	2.1	

Residential risks were assessed for both adults and toddlers based on guidance provided in the draft SOPs For Residential Exposure Assessment; the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version);* and data from submitted studies. HED considered several populations and exposure scenarios in this residential postapplication risk assessment as tetrachlorvinphos can be used in several ways that might potentially create a risk for a residential population. Home pet treatments were selected by HED as scenarios that are representative of tetrachlorvinphos risks in the residential environment. For the home use scenario, risks attributable to non-dietary ingestion and dermal exposure were also assessed for toddlers after contact with treated pets based on the guidance provided in the SOPs For Residential Exposure Assessment. Surface area calculations were based on information from the EPA's Exposure Factors Handbook (EPA, 1997) and transfer rate data from the studies.

Residential Postapplication was assessed as follows:

$$Exposure(mg / day) = \frac{AR * TR * SA(contact)}{SA(dog)}$$

Where: AR = Application Rate: average rate of application in studies,

TR = Transferable Residues: residue transferred in studies on DAT 0,

SA(contact) =Surface area: 400 cm² for adult petting dog, 1150 cm² representing a child hugging a dog;

89 cm² representing toddler hand petting dog for hand to mouth transfer,

SA(dog) = Surface Area 6000 cm² surface area of a medium sized dog,

Body Weight = 70 kg for Adult; and 15 kg for toddler.

and

Dose $(mg/kg/day) = Exposure (mg/day) * Absorption <math>\div Body Weight$

Where: Absorption = Dermal Absorption of 9.57 %/100 or Oral Absorption of 100%/100

The surface area for the toddler hugging a treated dog was calculated using the surface area of a 2-3 year old child, approximately 6000 cm², one quarter of which is not covered by

clothes, 1500 cm². One-half of the exposed surface area is in contact with treated pet, 750 cm², plus one half of the head 400 cm². From this extrapolation of information from the Exposure Factors Handbook, the exposed surface area for a child hugging or sleeping with a dog becomes 1150 cm².

Toddler Hand-to-Mouth exposure from Residential Exposures Assessment SOPs was calculated as follows:

Toddler hand to mouth

= Transferable Residue x Extraction Rate x Application Rate x 89 cm²/event x 1.56 event/hr x 2 hr/day 15kg x 6000 cm²/pet

Where: Extraction Rate = percent of ai removed by saliva, 50 percent/100.

Table 11 contains the residential postapplication exposure risks for tetrachlorvinphos product uses on pets. For the short- and intermediate-term assessment daily dose levels were compared directly to the short-and intermediate-term NOAEL of 4.23 mg/kg/day.

4 Risk Assessment

a. Summary of Total risks to Occupational Handlers

The Agency identified exposure scenarios based on available labels. As indicated, surrogate data were used to develop some of the exposure/risk assessments for occupational handlers. In addition, some chemical specific data were available for the occupational scenarios. However, in some cases appropriate surrogate data were not available to serve as the basis for an assessment. The scenarios for which no appropriate data were available are presented below (for both short- and intermediate-term exposures):

- application of dust to animals; and
- applying pellets for feed-through fly control.

<u>Baseline</u>: In cases where chemical-specific or appropriate surrogate data were available, a risk assessment was completed. The calculations of short- and intermediate-term total risks (i.e., toxicological endpoints are the same) indicate that the MOEs are more than 100 at the baseline clothing scenario for the following (see Table 4A):

- (I) Mixing/loading liquids for spray application;
- (II) Mixing/loading granules in feed;
- (IIIa) Mixing/loading wettable powder (MRID 426223-01), data includes use of chemical

resistant gloves;

- (IV) Applying aerosol spray;
- (VIIa) applying with a high pressure handwand (MRID 426223-01), data includes use of chemical resistant gloves; and
- (VIII) Low pressure handward (liquid, open pour).

PPE: In cases where additional PPE was applied the following scenarios obtained an exposure level with an MOE of more than 100. This level of additional PPE represents, a second layer of clothing (i.e., long sleeved shirt, long pants or coveralls), chemical resistant gloves and a dust/mist respirator (see Table 4B).

• (IIIb) Mixing/loading wettable powder.

Applying with a pressure handward obtained an MOE of 94 at this level of additional PPE, and with the addition of a second layer of clothes the MOE became 150.

<u>Engineering controls</u>: Engineering controls are not applicable for most of the scenarios, and when they are applicable (e.g., wettable powder in soluble bags) the mitigation is not necessary.

Regardless of the level of risk mitigation, by the addition of PPE, one exposure scenario's **MOE value never exceeded 100.** This scenario was:

• (IXa, IXb) Backpack sprayer.

b. Occupational Risk from Postapplication Exposure

As indicated in Section 2a, the Agency finds the use patterns of tetrachlorvinphos do not contain postapplication exposure risk in the occupational setting. Since there is no plant use for tetrachlorvinphos, and mechanized uses minimize exposure in feed lots, no REIs need to be assigned.

c. Occupational Carcinogenic Risk

At baseline values, all carcinogenic risks were between 7.8×10^{-8} to 6.5×10^{-5} except the backpack scenario. The exposure scenarios were amortized over the working lifetime of the applicator considering 6 months to one full year of tetrachlorvinphos use and those values were multiplied by the Q1* of 1.83×10^{-3} . When the range of use included 3 treatments per year, the backpack values at baseline fell to 1.7×10^{-5} (see Table 6 and 6A).

With the addition of PPE the values for the carcinogenic risk were between 2.4 x 10⁻⁷ to

 2.9×10^{-6} , and backpack carcinogenic risks fell between 4.2×10^{-5} and 1.5×10^{-4} . Again, to achieve a more moderate assessment, the exposures were amortized with PPE for three treatments per year resulting in carcinogenic risks between 2.7×10^{-8} to 8.6×10^{-6} for all values (see 7 and 7A).

d. Summary of Residential Handler Risk: Non-cancer

Chemical-specific data were available to support some pet treatments. Due to the low replicate numbers, poor quality control and analysis, HED used the average and maximum application to portray a range of residential handler exposures. All scenarios obtained MOEs >100 except the dip and powder application scenarios using the Residential SOPs and the dip scenario that incorporated the simulated dip with E-FAST dermal exposures. The MOEs range from 4 to 49 for these scenarios and the MOEs of the scenarios that were >100 ranged from 220 to 6100.

According to the *SOPs for Residential Exposure Assessment*, mitigation by addition of PPE is not appropriate in residential scenarios. Dip and flea collar residential handler exposure was based on the submitted studies and label uses for the product form. Powder handler exposure was calculated according to the *SOPs for Residential Exposure Assessment* (i.e., using 10 percent of the applied ai as the amount available for exposure for the applied products). PHED V1.1 was available for use for the aerosol and pump spray application scenarios.

d. Summary of Residential Handler: Carcinogenic Risk

Each scenario from the residential handler risk assessment was amortized to obtain the residential LADD. Carcinogenic risk was calculated by multiplying the residential LADD by the Q1* of 1.83×10^{-3} . As seen in Table 10, Residential SOPs calculations for large pet handler dip exposure and powder applications were the only residential application with a calculated carcinogenic risk exceeding 1×10^{-6} .

<u>e.</u> <u>Residential Postapplication Exposure: Non-cancer.</u>

Residential postapplication exposures were also assessed based on average and maximum DAT 0 percent transfer of application to gloves from submitted postapplication studies. Using study data, risks were assessed for adult and toddler exposures, including toddler hand-to-mouth exposures. The postapplication exposure assessment for toddlers assumes the dermal exposure one might expect if a child hugs the dog and a non-dietary oral (hand-to-mouth) dose if the child also pets the dog.

The following dermal algorithm was used:

$$mg / kg / day = \frac{AR \times DR \times HSA}{ASA \times BW (kg)}$$

Where:

AR = Amount of ai applied to treat a medium dog, study average and maximum values

DR = Percent Dislodgeable Residue from animal fur, study average and maximum values

HSA = Human Surface Area; 400 cm² for ½ of adult hands and 1150 cm² consisting of ½ arms, ½ hands and ½ torso for toddler.

ASA = Animal Surface Area (6000 cm2)

BW = Body Weight (70 kg for adult and 15 kg for toddler)

The following non-dietary (hand-to-mouth) algorithm was used:

$$mg / kg / day = \frac{AR \times DR \times HSA}{ASA \times BW (kg)} (x SE)$$

Where:

AR = Amount of ai applied to treat a medium size dog, study average and maximum values

DR = Percent Dislodgeable Residue from animal fur, study average and maximum values

HSA = Human Surface Area (89 cm2) consisting of ½ of one hand

ASA = Animal surface area (6000 cm2)

SE = Saliva Extraction (50%) based on solubility.

BW = Body Weight (15 kg)

Adult dermal postapplication exposure resulted in MOEs above 100; assessment of a toddler hugging a treated animal on DAT 0 resulted in MOEs form 93 to1600. Toddler hand-to-mouth exposure MOEs were found to be <u>under</u> 100 for maximum transfer rates of powder, aerosol and pump spray uses (MOEs 74 to 99); therefore, the Agency has concern for these exposures.

f. Residential Postapplication Exposure: Cancer

Postapplication exposures to adults were amortized over the lifetime of pet ownership to obtain the carcinogenic risk (see Table 12). The postapplication exposures were distributed over 7 days according to the calculated average and maximum percent transfer rate of residues in the postapplication studies. DAT 0, DAT1, DAT 3 and DAT 7 were collected data points; the transfer rates for the days in-between were calculated by dividing the difference of the transfer rates by the number of interceding days. The DAT0 to DAT 7 transfer rate values were then averaged to obtain the time weighted average (TWA) transfer rate over the first week after

treatment. Doses were calculated from the transfer rates for each day and similarly averaged to obtain a time weighted average (TWA) exposure. The TWA exposure values were multiplied by the Q_1^* of 1.83×10^{-3} and the number of days of exposure (number of treatments/year x 7-day average exposure-Table 12). Pet ownership was considered to be 50 years of a lifetime of 70 years. One pet treated per event was assumed. The residential carcinogenic risk for 1 treatment per year (obtaining 7 days of exposure) ranged from of 2.5×10^{-8} to 1.8×10^{-7} for TWA -average transfer rates and 5×10^{-8} to 2.8×10^{-7} for TWA -maximum transfer rates. For maximum treatments per year (10 uses for aerosols and pump sprays; 8 uses for powders), the carcinogenic risk ranged from 1.2×10^{-7} to 1.8×10^{-6} for the TWA -average transfer rates and 1.8×10^{-7} to 2.8×10^{-6} for the TWA -maximum transfer rate.

According to the Hartz market information, Hartz tetrachlorvinphos products make up less than 15 percent of the insecticidal products available to the pet owner. The market information supplied by Hartz gave general purchases of product packages over a year. The number of product packages purchased per year and the number of uses per package were the basis for the postapplication amortization for lifetime average daily dose and lifetime carcinogenic risk.

g. Combined Residential Carcinogenic Risk Assessments

The Handler and Postapplication carcinogenic risk values were combined to represent the use of a product plus the postapplication exposure to a pet owner. The use of multiple products was discussed by Hartz as most likely the use of a topical product plus use of a collar. Due to the low replicate numbers in the Hartz postapplication studies, average and maximum time-weighted average transfer rates were used to characterize a range of carcinogenic risk from use of multiple products. One use of a dip per year and 2 uses of the other products was employed to represent a more typical use pattern. The results for handler and postapplication carcinogenic risk combined ranged from 3.5×10^{-7} to 3.6×10^{-6} for the average transfer rate and 3.3×10^{-7} and 3.7×10^{-6} for the maximum transfer rate; for some product uses, the calculated risks exceeded the Agency's level of concern (see Table 13).

Use of a product and its postapplication exposure potential, with the addition of a exposure from application of a collar was also aggregated. This was described as the most likely combination of products by Hartz. The calculations yielded a carcinogenic risk range of, 4.6×10^{-7} to 3.7×10^{-6} for average transfer rates and 5.0×10^{-7} to 3.8×10^{-6} for maximum transfer rates. Some of the calculated risks for these combinations of products also exceeded the Agency's level of concern (1×10^{-6}) .

h. Residential Risk Assessment Characterization.

Certain factors must be considered when reviewing the data and calculations found in this exposure and risk assessment. Some of the issues are presented below:

• PHED 1.1 unit exposure values range between the geometric mean and the median of the available exposure data and calculate a central tendency value.

- Residential SOPs are believed to be a reasonable bounding estimate based on professional judgement and experience.
- Many problems were encountered using the studies submitted by Hartz such as, very low number of replicates, lack of quality control and analysis, use of non-end use product (water) and lack of method validation.
- Market data supplied by Hartz did not convey the typical use of pet insecticide products in the residential setting. The information was unclear as to how the products purchased reflected use of tetrachlorvinphos products. For this assessment, it was assumed that the typical number of product purchased were used in a calendar year.
- According to the market data, Hartz tetrachlorvinphos pet treatments represent about 15
 percent of the pet insecticidal products available. The use of only tetrachlorvinphos
 products in this setting seems unlikely. Market information given makes a more refined
 determination of use impossible.
- E-FAST was used to generate dermal exposure to hands during the dip process (residential scenario 2). The tool is based on Chemical Exposure Model (CEM) which has been released by the agency. E-FAST is currently undergoing peer review. Hand exposure was expected to be a significant source of dermal exposure for the dip scenario.

Secondary Review: J. Arthur, M.Collantes, 10/21/99.

References

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- 4. Versar, Inc. 1992b. A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. EPA Contract No. 68-02-4254.

 Table 4: Baseline Exposure Values for Occupational Uses of Tetrachlorvinphos

(Mixer/Loader/Applicator).

	Exposure Scenario		Unit Ex	posure		_	
No.	(Scen. #) ^a	Baseline ^b		Additional PPE ^c		Rates	
		Dermal (mg/lb ai)	Inhalation (µg/lb ai)	Dermal (mg/lb ai)	Inhal. (μg/lb ai)	Maximum Application Rate	Daily Max Treated ^d
		М	ixer/Loader Exp	osure			
I	Mixing/loading liquids for spray application	2.9	1.2	0.023	0.24	0.027 lb ai/cow	400 cattle
II	Mixing/loading granules in feed	0.0084	1.7	n/a	n/a	0.14 lb ai/cow	400 cattle
IIIa	Mixing/loading wettable powder (data from MRID 42622301)	0.3 (gloves)	24	n/a	n/a	40 lb ai/poultry house	1 poultry house
IIIb	Mixing/Loading wettable powder (data from PHED)	3.7 (no gloves)	43	0.17	8.6	40 lb ai/poultry house	1 poultry house
		ı	Applicator Expo	sure			
IV	Applying spray with Aerosol Can	172	2.43	n/a	n/a	0.00433 lb a.i/can	1 can
V	Applying dust with Dusters	No Data	No Data	n/a	n/a	No Data	No Data
VI	Applying Pellets	No Data	No Data	n/a	n/a	No Data	No Data
VIIa	Applying with a High Pressure Handwand (data from MRID 42622301)	0.6 (gloves)	0.006	n/a	n/a	40 lb ai/poultry house	1 poultry house
VIIb	Applying with a High Pressure Handwand (data from PHED 1.1)	1.8	79	0.37	16	40 lb ai/poultry house	1 poultry house
		Mix	er/Loader/Ap	plicator			
VIII	Low Pressure Handwand (liquid open/pour)	102	0.030	0.43	0.0060	1.4 lb active ingredient/A	2.5 acre ^f
IXa	Backpack ^e	483	0.330	234	0.066	1.4 lb ai/A	2.5 acre ^f
IXb	Backpack, double layer clothes, gloves	n/a	n/a	136	0.066	1.4 lb ai/A	2.5 acre ^f

a NOTE: Scenarios are from PHED for scenarios IIIb and VIIb.

Baseline -- workers wearing single layer clothing, no gloves and no respirator. Workers wore chemical-resistant gloves for scenario numbers IIIb and VII (from MRID 42622301

c Additional PPE – workers typically wear long-sleeved shirt, long pants (double layer of clothing where noted), chemical resistant gloves, and dust/mist respirator. Specific PPE listed in Table 5 for each scenario.

d Values represent the maximum area (number of animals) which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

e Backpack is applicator only, not mixer/loader/applicator due to low confidence data and lack of hand data for liquid (open/pour) backpack. See Table 5 for data quality for backpack applicator.

f The available information indicates that approximately 2.5 acres is appropriate.

Table 4A: Baseline Occupational Handler Short and Intermediate Dermal and Inhalation Exposures to

Tetrachlorvinphos.

No.	Exposure Scenario	Daily Exposure (mg/day) ^a			Absorbed Daily Dose (mg/kg/day) ^b			Short/Int. Term MOE ^c
		Dermal	Inhalation	Total	Dermal	Inhalation	Total	
			Mixer	Loader Expo	sure			
I	Mixing/loading liquids for spray application	31	0.0013	31	0.043	1.9 x 10 ⁻⁴	0.043	100
II	Mixing/loading granules in feed	0.47	0.095	0.57	6.4 x 10 ⁻⁴	1.4 x 10 ⁻³	2.0 x 10-3	2100
IIIa	Mixing/loading wettable powder (data from MRID 42622301)	12	0.96	13	0.016	0.014	0.030	140
IIIb	Mixing/Loading wettable powder (data from PHED)	148	1.7	150	0.20	0.025	0.23	19
			Appl	licator Exposi	ıre			
IV	Applying spray with Aerosol Can	0.74	0.01	0.75	1.0 x 10 ⁻³	1.5 x 10 ⁻⁴	1.2 x 10 ⁻³	3700
V	Applying dust with Dusters	No data	No data	No data	No data	No data	No data	No data
VI	Applying Pellets	No data	No data	No data	No data	No data	No data	No data
VIIa	Applying with a High Pressure Hand Wand (data from MRID 42622301)	24	0.24	24	0.033	3.4 x10 ⁻³	0.036	120
VIIb	Applying with a High Pressure Hand Wand (data from PHED 1.1)	72	3.2	75	0.098	0.045	0.14	30
VIIc	Applying with a High Pressure Handwand (data from PHED 1.1, double layer clothes, dust/mist respirator)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			Mixer/	Loader/Appli	cator			
VIII	Low Pressure Handwand (liquid open/pour)	357	0.11	357	0.49	1.5 x 10 ⁻³	0.49	876
IXa	Backpack	1690	1.2 x 10 ⁻³	1690	2.3	1.7 x10 ⁻⁵	2.3	1.8
IXb	Backpack (data from PHED 1.1, double layer clothes, dust/mist respirator)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

[&]quot;No data" indicates that no appropriate data are available for incorporation into this cell. "N/A" indicates that this scenario is not appropriate in this table.

a Daily Dermal Exposure (mg/day)= Baseline Dermal Unit Exposure*Max. Label App. Rate* Daily Max Treated
Daily Inhalation Exposure (mg/day)= Baseline Inhalation Unit Exposure*Max. Label App. Rate* Daily Max Treated*1mg/1000 µg
Total Daily Exposure (mg/day) = Daily Dermal Exposure + Daily Inhalation Exposure.

b Absorbed Dermal Daily Dose (mg/kg/day) = Daily Dermal Exposure (mg/day) * dermal absorption (9.57% /100) / body weight (70kg) Absorbed Inhalation Daily Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day) / body weight (70kg) Total Absorbed Daily Dose (mg/kg/day) = absorbed dermal daily dose + absorbed inhalation daily dose.

c Short/Intermediate Term MOE = NOAEL/Total Daily Absorbed Dose. NOAEL = 4.23 mg/kg/day.

Table 4B: Occupational Handler Short-term and Intermediate-term Risks from Tetrachlorvinphos with Additional PPE.

No.	Exposure Scenario ^a	Daily Exposure with Additional PPE ^b (mg/day)			Absorbed Dose with Additional PPE ^c (mg/kg/day)			Additional PPE Short/Int.	
110.		Dermal	Inhalation	Total	Dermal	Inhalation	Total	Term MOE	
			Mixer/Loader	r Exposure					
I	Mixing/loading liquids for spray application	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
II	Mixing/loading granules in feed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
IIIa	Mixing/loading wettable powder (data from MRID 42622301)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
IIIb	Mixing/Loading wettable powder (data from PHED)	6.8	0.35	7.1	9.3 x 10 ⁻³	5.0 x 10 ⁻³	0.014	300	
			Applicator l	Exposure					
IV	Applying spray with Aerosol Can	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
V	Applying dust with Dusters	No data	No data	No data	No data	No data	No data	No data	
VI	Applying Pellets	No data	No data	No data	No data	No data	No data	No data	
VIIa	Applying with a High Pressure Handwand (data from MRID 42622301)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
VIIb	Applying with a High Pressure Handwand (data from PHED 1.1)	26	0.64	27	0.036	0.0091	0.045	94	
VIIc	Applying with a High Pressure Handwand (data from PHED 1.1, double layer clothes, dust/mist respirator)	14	0.64	15	0.019	0.0091	0.028	150	
			Mixer/Loader	/Applicator					
VIII	Low Pressure Handwand (liquid open/pour)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
IXa	Backpack	819	0.23	819	1.1	3.3 x 10 ⁻³	1.1	3.8	
IXb	Backpack, double layer clothes, gloves, dust/mist respirator	476	0.23	476	0.66	3.3 x 10 ⁻³	0.66	6.4	

"No data" indicates that no appropriate data are available for incorporation into this cell. "N/A" indicates that no further risk assessment is required for this scenario (i.e., an appropriate risk level has been attained prior to application of the current mitigation level).

a Exposure data is from PHED 1.1, for single layer clothes (i.e.,long sleeved shirt, long pants) and additional PPE specifically chemical resistant gloves, and a dust/mist respirator. Scenarios VIIc and IXb which consider, double layer of clothes, chemical resistant gloves and a dust/mist respirator. See Table 5 for description.

b Additional PPE Daily Dermal Exposure (mg/day)=Additional PPE Dermal Unit Exposure*Max. Label App. Rate* Daily Max Treated Additional PPE Daily Inhalation Exposure (mg/day)=Additional PPE Inhalation Unit Exposure*Max. Label App. Rate* Daily Max Treated PPE Total Daily Exposure (mg/day) = Additional PPE Daily Dermal Exposure + Additional PPE Daily Inhalation Exposure.

c Absorbed Dermal Daily Dose (mg/kg/day) = Daily Dermal Exposure (mg/day) * dermal absorption (9.57% /100) / body weight (70kg) Absorbed Inhalation Daily Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day) / body weight (70kg) Total Absorbed Daily Dose (mg/kg/day) = absorbed dermal daily dose + absorbed inhalation daily dose.

d Short/Intermediate Term MOE = NOAEL/Total Daily Absorbed Dose. NOAEL = 4.23 mg/kg/day.

Table 5: Exposu	Table 5: Exposure Scenario Descriptions for Tetrachlorvinphos										
Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Assumptions ^b	Comments ^c						
	Mixer/Loader Exposure										
Mixing/loading liquids for spray application (I)	PHED V1.1	Baseline: Long Pants, Long- Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves, dust/mist respirator	Open Mixing/Loading	Treat cattle every 10 days for 6 months (i.e., 18 treatments) OR Treat cattle every 10 days for 12 months (i.e., 36 treatments)	Baseline: Hands, dermal, and inhalation acceptable grades; Dermal = 71 - 121 replicates; Hands = 53 replicates; Inhalation = 53 replicates; High confidence in dermal, hand, and inhalation data PPE: Hands, dermal, and inhalation acceptable grades; Dermal = 71 - 121 replicates; Hands = 59 replicates; Inhalation = 53 replicates; High confidence in dermal, hand, and inhalation data A 80% PF was applied to the inhalation exposure to account for the use of a dust/mist respirator.						
Mixing/loading Granules in feed (II)	PHED V1.1	Baseline: Long Pants, Long- Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves, dust/mist respirator	Open Mixing/Loading	Feed to cattle every 10 days for 6 months (i.e., 18 treatments) OR Feed to cattle every 10 days for 12 months (i.e., 36 treatments)	Baseline: Hands = All grades; Hands = 10 replicates; Dermal = ABC grades; Dermal = 33 to 78 replicates; Low confidence in dermal and hands due to poor grade quality of the hand replicates and low replicate numbers. Inhalation = acceptable grades; Inhalations = 58 replicates; High confidence in inhalation data PPE: Dermal = ABC; dermal = 33 - 78 replicates; Hands = acceptable grades; Hands = 45 replicates; medium confidence in hands and dermal; inhalation = 58 replicates; inhalation = acceptable grades; High confidence in inhalation data. A 80% PF was applied to the inhalation exposure to account for the use of a dust/mist respirator.						
Mixing/loading wettable powders (IIIa)	MRID 426223-01	Single Layer Coveralls, Gloves	Open Mixing/Loading	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments) OR Treat once every 14 days for 12 months (26 treatments)	Acceptable grades (pending verification of storage stability); Dermal and inhalation = 16 replicates; High confidence in data (based on preliminary findings)						

Table 5: Exposure Scenario Descriptions for Tetrachlorvinphos Clothing Scenario Exposure Scenario Data Equipment Assumptions^b Comments^c (Scen. #) Source Exposure Scenario Clothing Scenario Equipment Assumptions^b Comments^c Data (Scen. #) Source Mixing/loading wettable PHED Baseline: Long 4 lb ai/100 gal; **Baseline:** Dermal and Hands = ABC; dermal = 22 - 45 replicates; hands = 7 Open powders (IIIb) V1.1 Pants, Long-Mixing/Loading 1 gal/100 birds; replicates; low confidence in dermal and hands due to the low number of hand Sleeved Shirt, No 100,000 birds/facility; replicates; Inhalation = ABC; Inhalation = 44 replicates; Medium confidence in Gloves treat once every 14 days for 6 inhalation data months (13 treatments) PPE: Long Pants, **PPE:** Dermal, hands, and inhalation = ABC, dermal = 22 - 45 replicates; hands = 24 OR Long-Sleeved replicates; inhalation = 44 replicates; medium confidence in dermal, hands, and Shirt, Gloves, inhalation data A 80% PF was applied to the inhalation exposure to account for the dust/mist Treat once every 14 days for use of a dust/mist respirator. 12 months (26 treatments) respirator Applicator Exposure PHED Applying spray with Baseline: Long Aerosol Can 1 can - 1 animal treated once **Baseline:** Dermal = 30 replicates; dermal = ABC; hand = 15 replicates; hand = A. aerosol can (IV) V1.1 Pants, Longper week for 6 months (26 Inhalation = 30 replicates; Inhalation = ABC; Medium confidence in inhalation, Sleeved Shirt, No treatments) dermal and hand data. Gloves OR **PPE:** Dermal = 30 replicates; dermal = ABC; hand = 15 replicates; hand = A. PPE: Long Pants, Inhalation = 30 replicates; Inhalation = ABC; Medium confidence in inhalation, Long-Sleeved 1 can - 1 animal treated once dermal and hand data. A 80% PF was applied to the inhalation exposure to account for Shirt, Gloves, per week for 12 months (52 the use of a dust/mist respirator. dust/mist treatments) respirator Animal dusters (V) No Data No Data No Data No Data No Data Applying pellets(VI) No Data No Data No Data No Data No Data MRID 4 lb ai/100 gal; MRID 426223-01: Acceptable grades, Dermal and inhalation = 16 replicates; High Applying with High a: Single Layer Wandtype Sprayers, 1 gal/100 birds; confidence in data (based on preliminary findings) Pressure Handwand 426223-01 Coveralls, Gloves Coarse Spray, Single (VIIa.) Nozzle, 100 ft. long 100,000 birds/facility: treat once every 14 days for 6 hose months (13 treatments) OR Treat once every 14 days for 12 months (26 treatments)

Table 5: Exposure Scenario Descriptions for Tetrachlorvinphos Clothing Scenario Assumptions^b Exposure Scenario Data Equipment Comments^c Source (Scen. #) Applying with High PHED V b: single layer Wandtype Sprayers, 4 lb ai/100 gal;1 gal/100 PHED V1.1: **Baseline:** Dermal = 9 replicates; all grades; hand = 2 replicates; all Pressure Handwand Coarse Spray, Single grade. Inhalation = 11 replicates, all grades. Low confidence in inhalation, dermal 1.1 clothes, gloves, (VIIb, VIIc) dust/mist Nozzle, 100 ft. long 100,000 birds/facility; and hand data, due to inadequate replicate numbers and poor grade quality. treat once every 14 days for 6 Additionally, the gloved hand values are based primarily on non-detects. For respirator; hose months (13 treatments) additional PPE a 80% PF was applied to the inhalation value to account for the use of c: double layer the dust/mist respirator, and in VIIc a 50%PF was applied to the upper and lower arm, clothes, gloves, OR chest, back, thigh and lower leg dermal exposure to account for the use of the double dust/mist respirator layer of clothes. Treat once every 14 days for 12 months (26 treatments) Mixer/Loader/Applicator PHED Low Pressure Handwand Baseline: Long 2 to 3 gallon low 1 acre treated once per week **Baseline:** Inhalation = 80 replicates; Inhalation = ABC; dermal = 9 - 80 replicates; V1.1 for 6 months (26 treatments) dermal = ABC; hands = 70 replicates; hands = all grades; Low confidence in hands (VIII) Pants, Longpressure single wand Sleeved Shirt, No and dermal data due to inadequate replicate number and low hand grades used (lots of Gloves OR E data). Medium confidence in inhalation data. **PPE:** Inhalation = 80 replicates; Inhalation = ABC; dermal = 13 replicates; dermal = PPE: Long Pants, 1 acre treated once per week Long-Sleeved for 12 months (52 treatments) C; hands = 10 replicates; hands = ABC; Low confidence in hands and dermal data due Shirt, Gloves, to inadequate replicate number. Medium confidence in inhalation data. A 80% PF was applied to the inhalation exposure to account for the use of a dust/mist respirator. dust/mist respirator

Table 5: Exposure Scenario Descriptions for Tetrachlorvinphos

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Assumptions ^b	Comments ^c
Backpack (IX)	PHED V1.1	Baseline: Long Pants, Long- Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves, dust/mist respirator	2 gallon backpack	1 acre treated once per week for 6 months (26 treatments) OR 1 acre treated once per week for 12 months (52 treatments)	No Clothing: Dermal and hands = 69, AB grade, acceptable; dermal = 69 replicates, hand = 60 replicates. High confidence in hands and dermal data Baseline: Head and Neck, and Hands =AB grade; 69 replicates(hand and neck only); high confidence in hands and neck, low confidence on dermal data. A 50% protection factor (PF) was applied on dermal Upper and Lower Arm, Chest, Back, Thigh, and Lower Leg-minimal clothing exposures to simulate baseline clothing (Long sleeve shirt, long pants, no gloves: i.e. 394mg/lb ai *0.5= 195 mg/lb ai handled was then added to the hand and face and neck exposure = dermal exposure considering the one layer of clothing) Inhalation = acceptable grades; Inhalation = 40 replicates High confidence in inhalation data. PPE: Dermal and Hands = Acceptable grades; dermal = 69 replicates; hands = 60 replicates; high confidence in hands and dermal data. A 50% protection factor (PF) was applied on dermal Upper and Lower Arm, Chest, Back, Thigh, and Lower Leg, baseline clothing exposures to simulate PPE clothing (Long sleeve shirt, long pants, gloves). An additional 50% PF was applied on the Baseline Clothes value to account for Double Layer Clothes and a PF of 90% applied to the Hand Dermal exposure for the chemical resistant glove in the last scenario. A 80% PF was applied to the inhalation exposure to account for the use of a dust/mist respirator. Inhalation = acceptable grades; Inhalation = 40 replicates High confidence in inhalation data.

a Clothing scenario represents actual monitored exposure data in MRID 426223-01.

Data confidence as reported in the Table refers to both the quality and the quantity (number of replicates) of data for each PHED run. Each study in PHED has been graded from A to E. A high confidence run is grades A and B data and 15 or more replicates per body part. Any combination of A and B grade data are listed as acceptable grades data in the tables. A medium confidence run is grades A, B, and C data and 15 or more replicates per body part. Any combination of A, B, and C grade data are listed as ABC grade data in the tables. A low confidence run is all grades (any run that includes D or E grade data) or has less than 15 replicates per body part.

b Standard Assumptions based on an 8-hour work day as estimated by HED. The label specifies that treatment with larvicidal feeds should begin early in the spring before flies begin to appear and continue feeding throughout the summer and into fall until cold weather restricts fly activity. Depending on the area of the US, this could be as short as a few months or could encompass most of the year. The six month and one year applications are used in calculating the Lifetime Average Daily Dose in Tables 6 and 7.

These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. A replicate refers to data acquired during one complete work cycle. All handler exposure assessments in this document are based on the "Best Available" data as defined by HED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments.) Best available grades are assigned as follows: matrices with grades A and B data (which is defined as acceptable grade data) and a minimum of 15 replicates; if not available, then all data (all grades) regardless of the quality and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor.

Table 6: Bas	_	nic Risk Estimates f trachlorvinphos.	or Occupationa	l Uses of
	Total Daily	Amortization ^b	Mixer/Lo	pader/Applicator
Exposure Scenario (Scenario #)	Dose ^a (mg/kg/day)		LADD ^c (mg/kg/day)	Carcinogenic Risk ^d
		Mixer/Loader Exposure		
Liquids (I)	0.043	$\left(\frac{18 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	1.1 x 10 ⁻³	1.9 x 10 ⁻⁶
		$\left(\frac{36 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	2.1 x 10 ⁻³	3.9 x 10 ⁻⁶
Granules (II)	0.002	$\left(\frac{18days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	4.9 x 10 ⁻⁵	9.0 x 10 ⁻⁸
		$\left(\frac{36 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	9.9 x 10 ⁻⁵	2.0 x 10 ⁻⁷
Wettable Powder (IIIa) MRID 42622301 (gloves)	0.030	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	5.2 x 10 ⁻⁴	9.0 x 10 ⁻⁷
		$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.1 x 10 ⁻³	2.0 x 10 ⁻⁶
Wettable Powder (IIIb) PHED (no gloves)	0.23	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	3.9 x 10 ⁻³	7.2 x 10 ⁻⁶
		$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	8.2 x 10 ⁻³	1.5 x 10 ⁻⁵
		Applicator Exposure		
Aerosol Can (IV)*	0.0012	$\left(\frac{26 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	4.3 x 10 ⁻⁵	7.8 x 10 ⁻⁸
		$\left(\frac{52days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	8.6 x 10 ⁻⁵	2.0 x 10 ⁻⁷
Dusters (V)*	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data
Power Sprayers (VII)	0.036	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	6.4 x 10 ⁻⁴	1.2 x 10 ⁻⁶
		$\left(\frac{26 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	1.3 x 10 ⁻³	2.3 x 10 ⁻⁶
	N	/lixer/Loader/Applicator		
Low Pressure Handwand (VIII)	0.50	$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	0.018	3.3 x 10 ⁻⁵
		$\left(\frac{52days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	0.036	6.5 x 10 ⁻⁵
Backpack (IX)	2.3	$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	0.083	1.5 x 10 ⁻⁴
		$\left(\frac{52days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	0.16	3.0 x 10 ⁻⁴

Absorbed Total Daily Dose was estimated in Table 4A

Table 6A: LADD and Carcinogenic Risk Amortized for 3 uses per year over working career.

Amortization represents maximum label use for one half or full year treatments as set out in Table 5. LADD (mg/kg/day) = [Daily Dermal Dose + Daily Inhalation Dose(mg/kg/day)] * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs). Risk = LADD (mg/kg/day) * (Q_1 *); where Q_1 * = 1.83 x 10⁻³ mg/kg/day⁻¹. c d

Exposure Scenario	Total Daily	Amortization ^b	Mixer/Lo	oader/Applicator
(Scenario #)	Dose ^a (mg/kg/day)		LADD ^c (mg/kg/day)	Carcinogenic Risk ^d
	<u>.</u>	Mixer/Loader Exposure		
Liquids (I)	0.043	$\left(\frac{3 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	1.8x 10 ⁻⁴	3.2 x 10 ⁻⁷
Granules (II)	0.002	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	8.2 x 10 ⁻⁶	1.5 x 10 ⁻⁸
Wettable Powder (IIIa) MRID 42622301 (gloves)	0.030	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.2 x 10 ⁻⁴	2.2 x 10 ⁻⁷
Wettable Powder (IIIb) PHED (no gloves)	0.23	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	9.0 x 10 ⁻⁴	1.7 x 10 ⁻⁶
		Applicator Exposure		
Aerosol Can (IV)*	0.0012	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	4.9 x 10 ⁻⁶	9.0 x 10 ⁻⁹
Dusters (V)*	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data
Power Sprayers (VII)	0.036	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.5 x 10 ⁻⁴	2.7 x 10 ⁻⁷
		Mixer/Loader/Applicator		
Low Pressure Handwand (VIII)	0.50	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	2.1 x 10 ⁻³	3.8 x 10 ⁻⁶
Backpack (IX)	2.3	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	9.5 x 10 ⁻³	1.7 x 10 ⁻⁵

a Absorbed Total Daily Dose was estimated in Table 4A

b Amortization represents 3 treatments per year, during a 35 year career within a 70 year lifespan.

 $c \hspace{1.5cm} LADD \hspace{0.1cm} (mg/kg/day) = [Daily \hspace{0.1cm} Dermal \hspace{0.1cm} Dose + \hspace{0.1cm} Daily \hspace{0.1cm} Inhalation \hspace{0.1cm} Dose (mg/kg/day)] \hspace{0.1cm} * \hspace{0.1cm} (Work \hspace{0.1cm} Days \hspace{0.1cm} Per \hspace{0.1cm} Yr/365 \hspace{0.1cm} Days \hspace{0.1cm} Per \hspace{0.1cm} Year) \hspace{0.1cm} * \hspace{0.1cm} (35 \hspace{0.1cm} Yrs/70 \hspace{0.1cm} Yrs). \hspace{0.1cm} + \hspace{0.1cm} Per \hspace{0.1cm} Yr/365 \hspace{0.1cm} Days \hspace{0.1cm} Per \hspace{0.1cm} Year) \hspace{0.1cm} * \hspace{0.1cm} (35 \hspace{0.1cm} Yrs/70 \hspace{0.1cm} Yrs). \hspace{0.1cm} + \hspace{0.1cm} Per \hspace{0.1cm} Yrs/70 \hspace{0.1cm} Yrs/70 \hspace{0.1cm} Yrs). \hspace{0.1cm} + \hspace{0.1cm} Per \hspace{0.1cm} Yrs/70 \hspace{$

d Risk = LADD (mg/kg/day) * (Q $_1$ *); where Q $_1$ * = 1.83 x 10 $^{\text{-}3}$ mg/kg/day $^{\text{-}1}$.

Table 7: PPE (Personal Protective Equipment) Carcinogenic Risk Estimates for Occupational

Uses of Tetrachlorvinphos

No.	Exposure Scenario (Scenario #)	Total Daily Dose ^a (mg/kg/day)	Amortization	LADD ^b (mg/kg/day)	Carcinogenic Risk ^c
			lixer/Loader	•	•
I	Mixing/loading Liquids for spray application	N/A	N/A	N/A	N/A
II	Mixing/loading Granules in feed	N/A	N/A	N/A	N/A
IIIa	Mixing/loading Wettable Powder (MRID 426223-01)	N/A	N/A	N/A	N/A
IIIb	Mixing/loading Wettable Powder (IIIb)	0.014	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	2.4 x 10 ⁻⁴	4.6 x 10 ⁻⁷
	PHED		$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	5.0 x 10 ⁻⁴	9.1 x 10 ⁻⁷
		Appl	icator Exposure		
IV	Applying Spray with Aerosol Can	N/A	$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	N/A	N/A
			$\left(\frac{52days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$		
V	Applying dust with Duster	No Data	No Data	No Data	No Data
VI	Applying Pellets	No Data	No Data	No Data	No Data
VIIa	Applying with a High Pressure Handwand (MRID 426223-01)	N/A	N/A	N/A	N/A
VIIb	Applying with a High Pressure Handwand	0.044	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	7.8 x 10 ⁻⁴	1.4 x 10 ⁻⁶
			$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.6 x 10 ⁻³	2.9 x 10 ⁻⁶
VIIc	Applying with a High Pressure Handwand	0.029	$\left(\frac{13 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	5.2 x 10 ⁻⁴	9.5 x 10 ⁻⁷
			$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.0 x 10 ⁻³	1.9 x 10 ⁻⁶
		Mixer/l	Loader/Applicator		
VIII	Low Pressure Handwand (liquid open/pour)(VIII)	0.0036	$\left(\frac{26days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.3 x 10 ⁻⁴	2.4 x 10 ⁻⁷
			$\left(\frac{52 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	2.6 x 10 ⁻⁴	4.7 x 10 ⁻⁷
IXa	Backpack (IX), single layer, gloves	1.14	$\left(\frac{26 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	4.1 x 10 ⁻²	7.4 x 10 ⁻⁵
			$\left(\frac{52 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	8.1 x 10 ⁻²	1.5 x 10 ⁻⁴
IXb	Backpack (IX), double layer, gloves	0.65	$\left(\frac{26 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	2.3 x 10 ⁻²	4.2 x 10 ⁻⁵
			$\left(\frac{52 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	4.6 x 10 ⁻²	8.4 x 10 ⁻⁵

a Total Daily Absorbed Dose from Table 4B (mg/kg/day) = Absorbed Daily Dermal Dose + Absorbed Daily Inhalation Dose

b LADD (mg/kg/day) = [Total Daily Dose(mg/kg/day)] * (Application Work Days/365 Days Per Year) * (35 Yrs/70 Yrs)

c Risk = LADD (mg/kg/day) * $(Q_1 *)$; where $Q_1^* = 1.83 \times 10^{-3} \text{ mg/kg/day}^{-1}$.

Table 7A: LADD and Carcinogenic Risk with PPE mitigation amortized for 3 use days per year over career.

No.	Exposure Scenario (Scenario #)	Total Daily Dose ^a (mg/kg/day)	Amortization	LADD ^b (mg/kg/day)	Carcinogenic Risk ^c
		M	lixer/Loader		
I	Mixing/loading Liquids for spray application	N/A	N/A	N/A	N/A
II	Mixing/loading Granules in feed	N/A	N/A	N/A	N/A
IIIa	Mixing/loading Wettable Powder (MRID 426223-01)	N/A	N/A	N/A	N/A
IIIb	Mixing/loading Wettable Powder	0.014	$\left(\frac{3 days}{365 days/yr}\right)\left(\frac{35 yrs}{70 yrs}\right)$	1.4 x 10 ⁻⁴	2.6 x 10 ⁻⁷
	•	Appli	icator Exposure	•	•
IV	Applying Spray with Aerosol Can	N/A	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	N/A	N/A
V	Applying dust with Duster	No Data	No Data	No Data	No Data
VI	Applying Pellets	No Data	No Data	No Data	No Data
VIIa	Applying with a High Pressure Handwand (MRID 426223-01)	N/A	N/A	N/A	N/A
VIIb	Applying with a High Pressure Handwand	0.044	$\left(\frac{3 days}{365 days/yr}\right)\left(\frac{35 yrs}{70 yrs}\right)$	1.8 x 10 ⁻⁴	3.3 x 10 ⁻⁷
VIIc	Applying with a High Pressure Handwand	0.029	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.2 x 10 ⁻⁴	2.2 x 10 ⁻⁷
		Mixer/I	Loader/Applicator		
VIII	Low Pressure Handwand (liquid open/pour)(VIII)	2.4 x 10-3	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	1.5 x 10 ⁻⁵	2.7 x 10 ⁻⁸
IXa	Backpack (IX), single layer, gloves	1.1	$\left(\frac{3days}{365days/yr}\right)\left(\frac{35yrs}{70yrs}\right)$	4.7 x 10 ⁻³	8.6 x 10 ⁻⁶
IXb	Backpack (IX), double layer, gloves	0.65	$\left(\frac{3 days}{365 days/yr}\right) \left(\frac{35 yrs}{70 yrs}\right)$	2.8 x 10 ⁻³	5.0 x 10 ⁻⁶

a Total Daily Absorbed Dose from Table 4B (mg/kg/day) = Absorbed Daily Dermal Dose + Absorbed Daily Inhalation Dose

b LADD (mg/kg/day) = [Total Daily Dose(mg/kg/day)] * (Application Work Days/365 Days Per Year) * (35 Yrs/70 Yrs)

c Risk = LADD (mg/kg/day) * (Q_1) ; where $Q_1^* = 1.83 \times 10^{-3} \text{ mg/kg/day}^{-1}$.

Table 8: Residential Handler Exposure Assessment for Tetrachlorvinphos.

			Exposure Assessment for Tetraemoryniphos.							
Scenario		mg/lb ai or % Available for Dermal Exposure ^a	Inhalation (μg/lb ai) ^b	Application Rate ** (mg ai)	Dermal Exposure (mg/day) ^c	Inhalation exposure (mg/day) ^c	Absorbed Dermal Dose ^d (mg/kg/day)	Absorbed Inhalation Dose ^d (mg/kg/day)	Total Absorbed Dose ^e (mg/kg/day)	MOE ^f
Dip (1) Residential SOPs	1 gal	10	NA	1800	180	NA	0.25	NA	0.25	17
	4 gal	10	NA	7300	730	NA	1.0	NA	1.0	4
(2) Dip (4 gal)	AVG	0.93%*	NA	7300	68	NA	0.093	NA	0.093	46
	MAX	0.97%*	NA		71	NA	0.097	NA	0.097	44
(2) Dip Sponge-on (1 gal)	AVG	3.6%*	NA	1800	65	NA	0.086	NA	0.086	49
	MAX	3.7%*	NA		67	NA	0.089	NA	0.089	48
(3) Dip (4 gal)	AVG	0.064%	NA	7300	4.7	NA	0.0064	NA	0.0064	660
	MAX	0.11%	NA		8.0	NA	0.011	NA	0.011	390
(3) Dip Sponge-on (1 gal)	AVG	0.028	NA	1800	0.50	NA	0.00069	NA	0.00069	6100
	MAX	0.0448	NA		0.86	NA	0.0012	NA	0.0012	3600
(4) Collar	AVG	0.30%*	NA	3500	11	NA	0.014	NA	0.014	300
	MAX	0.42%*	NA		15	NA	0.020	NA	0.020	220
(5) Powder	AVG	10%	NA	1500	150	NA	0.20	NA	0.20	21
	MAX			1600	160	NA	0.22	NA	0.22	19
(6) Aerosol Spray ^e	AVG	250	660	540	0.30	0.00079	0.00040	0.00079	0.0012	3600
	MAX			600	0.33	0.00087	0.00044	0.00087	0.0013	3200
(7) Pump Spray	AVG]		380	0.21	0.00055	0.00029	0.00055	0.00084	5000
	MAX			400	0.22	0.00058	0.00030	0.00058	0.00088	4800

^{*} Average and Maximum percent transferred from Submitted Studies MRID 44859403, MRID 44895404 and MRID 44859405.

^{**} Average and Maximum application rate from submitted studies: MRID: 448954-03; 448594-05; 448954-09; 448594-07; 448954-06 respectively.

a Residential handler dermal unit exposure represents short pants, short-sleeved shirt, no gloves, and open mixing/loading.

b Residential handler inhalation unit exposure represents no respirator.

c Dermal or Inhalation Exposure (mg/day)= (mg/lb ai or percent transferred /100) * Application Rate (g ai) *Conversion factors Where conversion factors are lb/454g; 1mg/1000μg

d Absorbed Dermal Dose (mg/kg/day)= [Dermal Exposure (mg/day) * Dermal Absorption (9.57% /100)] ÷ Body Weight (70kg).

Absorbed Inhalation Dose (mg/kg/day) = [Inhalation Exposure (mg/day) * Inhalation Absorption (100% /100)] ÷ Body Weight (70kg)

e Total Absorbed Dose (mg/kg/day) = Absorbed Dermal Dose (mg/kg/day) + Absorbed Inhalation Dose (mg/kg/day).

 $MOE = NOAEL (4.23 \text{ mg/kg/day}) \div Total Absorbed Dose (mg/kg/day).$

f

Table 9: Residential Handler Scenario Descriptions for the Use of Tetrachlorvinphos.

Exposure Scenario (Number)	Data Source	Standard Assumptions (1 pet treatment per day)	Comments ^a					
			Mixer/Loader/Applicator Descriptors					
Dipping a Dog (1)	SOPs for Residential Exposure Assessments (7/97)	1 gallon of dip and 1 small dog is dipped	The SOPs For Residential Exposure Assessment served as the basis for this assessment (i.e., the assumptions that were used to predict exposures from pet use products in which a percentage of the application rate is the predictor of potential dermal dose). The scenario is based on the use of a residential clothing scenario (i.e., short pants, short-sleeved shirt, no gloves, no respirator). The refinement of the SOPs for Residential Exposure Assessment is such that further delineation based on clothing scenario is not					
		4 gallons of dip and 1 large dog is dipped	appropriate (i.e., to alter value based on use of short vs. long pants and long-sleeved vs. short-sleeved shirts). EPA Reg. 2596-119.					
Dipping a Dog(2)	MRID 44859404 and Exposure Fate Assessment Screening Tool	Sponge-On Method: 1 gallon of dip for 1 small pet	The studies mentioned were reviewed in section 2.d.i. Both studies used water to simulate the end-use product an replicates per study. Due to non-use of end product, low replicate numbers, and the lack of quality control and analys studies, the maximum and average range of exposures was used to characterize residential exposures. No data was obt hand exposure during dip procedure therefore, further characterization of hand exposure was added, using the E-FAST Whether this results in an over- or under-estimate is unclear.					
	MRID 4485 9403 and Exposure Fate Assessment Screening Tool	Pour-On Method 4 gallons of dip for 1 large pet	Whether this results in an over- or under-estimate is unclear. EPA Reg. No. 2596-119.					
Dipping a Dog(3)	MRID 44859404	Sponge-On Method: 1 gallon of dip for 1 small pet	The studies mentioned were reviewed in section 2.d.i. Both studies used water to simulate the end-use product and only 4 replicates per study. Due to low replicate numbers, and the lack of quality control and analysis in the studies, the maximum and average range of exposures was used to characterize residential exposures. Due to the lack of guideline requirements these					
	MRID 44859403	Pour-On Method 4 gallons of dip for 1 large pet	studies are only presented in the Residential Handler Exposure Assessment. The studies were set out for COMPARISON PURPOSES ONLY. EPA Reg. No. 2596-119.					
Collar (4) Application	MRID 44859402	2 collar/year	The studies mentioned have been reviewed in section 2.d.i. Both studies applied collars while applicator wore cotton gloves. In one study the applicator wiped the gloved hand down the length of the collar to maximize exposure and simulate first time user. The average and maximum transfer rate of the wipe down method was used to evaluate residential exposure to ai in a collar.					
	MRID 44859405		Only 6 replicates per study and the quality control and analysis was lacking in the studies. EPA Reg No.2596-62,-63,-139.					
Powder(5)	SOPs for Residential Exposure Assessments (7/97)	Average and Maximum application rate from postapplication study (MRID 44859409)	Label directions for application state fractions of an ounce of product depending on size of pet. The postapplication study weighed product before and after application and gave the amount of product applied for residential application to a pet. The scenario is based on the use of a residential clothing scenario (i.e., short pants, short-sleeved shirt, no gloves, no respirator). The refinement of the SOPs for Residential Exposure Assessment is such that further delineation based on clothing scenario is not appropriate (i.e., to alter value based on use of short vs. long pants and long-sleeved vs. short-sleeved shirts). EPA Reg No. 2596-78,-79; 4691-138.					
Aerosol Spray(6)	PHED V1.1	Average and Maximum application rate from postapplication study (MRID 44859407)	Label directions for application state seconds of spray depending on size of pet. The postapplication study weighed the product before and after application and gave the only application data available for residential application to a pet. The PHED V1.1 baseline for dermal exposure with no clothes is 390 mg/lb ai applied, and with single layer clothes (long sleeve, long pants, no gloves) is 170 mg/lb ai. Considering Residential Clothing scenario of short sleeves and short pant, a value of dermal exposure was chosen as the difference between these two clothing scenarios, 220 mg/lb ai. Both PHED scenarios had Dermal replicates=30, ABC grade and Hand replicates = 15, Grade A, Medium confidence. Inhalation also taken from PHED, represents no respirator, had 30 replicates, ABC grade, medium confidence. EPA Reg. No. 2596-122.					

Exposure Scenario (Number)	Data Source	Standard Assumptions (1 pet treatment per day)	Comments ^a
Pump Spray (7)	PHED V1.1	Average and Maximum application rate from postapplication study (MRID 44859406)	Label directions for application state increasing number of pumps for increasing sizes of pet. The postapplication study weighed the product before and after application. That data will be used to determine maximum and average application rates. The PHED V1.1 baseline for dermal exposure with no clothes is 390 mg/lb ai applied, and with single layer clothes (long sleeve, long pants, no gloves) is 170 mg/lb ai. Considering Residential Clothing scenario of short sleeves and short pant, a central tendency value calculated from PHED aerosol application studies considering bare forearms and lower legs was calculated to be 250 mg/lb ai. Both PHED scenarios had Dermal replicates=30, ABC grade and Hand replicates = 15, Grade A, Medium confidence. Inhalation also taken from PHED was recalculated for residential default respiratory rate of 16.7 l/min resulting in 660 μg/lb ai; represents no respirator, had 30 replicates, ABC grade, medium confidence. The refinement of the SOPs for Residential Exposure Assessment is such that further delineation based on clothing scenario is not appropriate (i.e., to alter value based on use of short vs. long pants and long-sleeved vs. short-sleeved shirts). EPA Reg. No. 2596-126,-125.

a All Standard Assumptions are based on an 8-hour work day as estimated by HED. BEAD data were not available.

All handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:

High = grades A and B and 15 or more replicates per body part

Medium= grades A, B, and C and 15 or more replicates per body part

Low= grades A, B, C, D and E or any combination of grades with less than 15 replicates.

c PHED grading criteria do not reflect overall quality of the reliability of the assessment. Sources of the exposure factors should also be considered in the risk management decision

Table 10: Residential Handler Scenarios-Carcinogenic Risk for Residential Uses of Tetrachlorvinphos								
Use	Average Absorbed	Amorti	ization	LADD ^b	Carcinogenic Risk ^c			
	Daily Dose (mg/kg/day)ª	treatment days/year	years of lifetime	(mg/kg/day) Amortization				
Dip Residential SOPs (1)	Pour-On Method (large pet)	1day 365days/yr	50/70	0.0020	3.6 x 10 ⁻⁶			
	1.0	2day 365days / yr		0.0039	7.1 x 10 ⁻⁶			
	Sponge-On Method (small pet)	1day 365days/yr		0.00049	9.0 x 10 ⁻⁷			
	0.25	2day 365days / yr		0.00098	1.8 x 10 ⁻⁶			
(2)Dip- MRID 44859403 + E-FAST	Average Exposure Pour-On Method (large pet)	1day 365days / yr	50/70	1.8 x 10 ⁻⁴	3.3 x 10 ⁻⁷			
	0.093	2day 365days/ yr		3.6 x 10 ⁻⁴	6.7 x 10 ⁻⁷			
	Maximum Exposure Pour-On Method (large pet)	1day 365days / yr		1.9 x 10 ⁻⁴	3.5 x 10 ⁻⁷			
	0.097	2day 365days/yr		3.8 x 10 ⁻⁴	6.9 x 10 ⁻⁷			
(2)Dip MRID 44859404 +	Average Exposure Sponge-On Method (small pet)	1day 365days/ yr	50/70	1.7 x 10 ⁻⁴	3.1 x 10 ⁻⁷			
E-FAST	0.086	2day 365days/yr		3.4 x 10 ⁻⁴	6.2 x 10 ⁻⁷			
	Maximum Exposure Sponge-On Method (small pet)	1day 365days/ yr		1.7 x 10 ⁻⁴	3.2 x 10 ⁻⁷			
	0.089	2day 365days/yr		3.5 x 10 ⁻⁴	6.4 x 10 ⁻⁷			
Collar	Average Exposure 0.014	2days 365days/yr	50/70	5.5 x 10 ⁻⁵	1.0 x 10 ⁻⁷			
	Maximum Exposure 0.020	2days 365days/yr		7.7 x 10 ⁻⁵	1.4 x 10 ⁻⁷			
Powder	Average Exposure 0.21		50/70	8.0 x 10 ⁻⁴	1.5 x 10 ⁻⁶			
		8days		3.2 x 10 ⁻³	5.9 x 10 ⁻⁶			

Table 10: Residential Handler Scenarios-Carcinogenic Risk for Residential Uses of Tetrachlorvinphos							
Use	Average Absorbed	Amorti	ization	LADD ^b	Carcinogenic Risk ^c		
	(mg/kg/day) ^a	Daily Dose (mg/kg/day) ^a treatment years of days/year lifetime		(mg/kg/day) Amortization			
	Maximum Exposure 0.21	2days 365days / yr		8.3 x 10 ⁻⁴	1.5 x 10 ⁻⁶		
		8days 365days/yr		2.7 x 10 ⁻³	4.9 x 10 ⁻⁶		
Aerosol Spray	Average Exposure 0.0011	2days 365days/yr	50/70	4.1 x 10 ⁻⁶	7.5 x 10 ⁻⁹		
		10days 365days/yr		2.1 x 10 ⁻⁵	3.8 x 10 ⁻⁸		
	Maximum Exposure 0.0013	2days 365days/yr		5.1 x 10 ⁻⁵	9.4 x 10 ⁻⁹		
		10days 365days/yr		2.6 x 10 ⁻⁵	4.7 x 10 ⁻⁸		
Pump Spray	Average Exposure 0.00084	2days 365days / yr	50/70	3.3 x 10 ⁻⁶	6.0 x 10 ⁻⁹		
		10days 365days/yr		1.6 x 10 ⁻⁵	3.0 x 10 ⁻⁸		
	Maximum Exposure 0.00088	2days 365days / yr		3.5 x 10 ⁻⁶	6.3 x 10 ⁻⁹		
		10days 365days/yr		1.7 x 10 ⁻⁵	3.2 x 10 ⁻⁸		

Absorbed Daily Dermal Dose is from Table 8. LADD (lifetime average daily dose) = (absorbed daily dose)*(number of treatment days / 365days) *(50 years of pet ownership/70 year lifetime) Carcinogenic Risk = $(LADD)^*(Q_1^*)$, where the Q_1^* , is 1.83×10^{-3} (mg/kg/day)⁻¹ a b

Scenario ^a	Application Rate mg a.i. applied ^b	Transfer Rate (%)	Total daily	Total Daily Dose	MOE ^e
	mg a.i. appned	Rate (%)	exposure mg/day ^c	mg/kg/day ^d	
			Adult		
Dip-Average	1800	0.12	0.014	0.00020	21000
Dip -Maximum	1800	0.19	0.022	0.00031	14000
Powder Average	1500	1.6	0.15	0.0022	1900
Powder Maximum	1600	2.1	0.21	0.0031	1400
Aerosol Average	540	2.9	0.10	0.0014	3000
Aerosol Maximum	600	6.2	0.24	0.0034	1200
Pump Spray Average	380	4.7	0.11	0.0016	2600
Pump Spray Maximum	400	6.9	0.18	0.0025	1700
			Toddler		
Dip-Average	1800	0.12	0.040	0.0026	1600
Dip -Maximum	1800	0.19	0.063	0.0042	1000
Powder Average	1500	1.6	0.44	0.029	140
Powder Maximum	1600	2.1	0.62	0.041	100
Aerosol Average	540	2.9	0.29	0.019	220
Aerosol Maximum	600	6.2	0.68	0.046	93
Pump Spray Average	380	4.7	0.33	0.022	190
Pump Spray Maximum	400	6.9	0.51	0.034	130
		Toddle	er Hand to Moutl	h	
Dip-Average	1800	0.12	0.032	0.0021	1300
Dip -Maximum	1800	0.19	0.051	0.0034	800
Powder Average	1500	1.6	0.36	0.024	110
Powder Maximum	1600	2.1	0.50	0.033	82
Aerosol Average	540	2.9	0.23	0.016	180
Aerosol Maximum	600	6.2	0.55	0.037	74
Pump Spray Average	380	4.7	0.27	0.018	150
Pump Spray Maximum	400	6.9	0.41	0.027	99

a Scenarios are for medium pet (dog).

Application rate based on label as presented in studies. b

Total Daily Exposure(mg/day) = Surface Area (cm²) * Absorption* Application Rate (mg)* percent transferable DATO * events per day

6000 cm²

400 cm² representing adult petting dog (½ surface area of total hand); Surface Area =

1150 cm² representing a child hugging a dog (½ surface area of exposed skin, 50% of ½ of surface area under clothes); 89 cm² representing surface area of toddler hand in contact with dog for oral route.

9.57% for Dermal and 100% for Oral-with 50% removal efficiency. Absorption =

Events per day = 1.56 events per hour x 2 hour/day pet exposure (Toddler Hand-to-mouth only).

Total Daily Dose = Total Daily Exposure ÷ Body Weight (kg); where adult body weight = 70 kg and toddler body weight = 15 kg. d

Short term and Intermediate Term NOAEL = 4.23 mg/kg/day. MOE = NOAEL (mg/kg/day) - Total Daily Dose (mg/kg/day).

Table 12: Tetrachlo		-Application	Exposures	-Carcinogeni	ic Assessm	ent of Resid	lential Us	ses of				
Days After Treatment		Absorbed Dermal Dose by Scenario ^a (mg/kg/day)										
(DAT) ¹		j	Dip			Po	wder					
	A	Average	ı	Maximum	A	Average	N	1aximum				
	%	Dose	%	Dose	%	Dose	%	Dose				
Day 0	0.12	0.0030	0.19	0.0047	1.6	0.0083	2.1	0.011				
Day 1	0.083	0.0020	0.10	0.0025	0.59	0.0031	0.86	0.0045				
Day 2	0.046	0.0011	0.088	0.0022	0.42	0.0022	0.66	0.0034				
Day 3	0.040	0.00098	0.075	0.0018	0.25	0.0013	0.47	0.0024				
Day 4	0.030	0.00074	0.064	0.0016	0.22	0.0011	0.42	0.0022				
Day 5	0.020	0.00049	0.053	0.0013	0.19	0.0010	0.37	0.0019				
Day 6	0.010	0.00025	0.042	0.0010	0.16	0.00083	0.32	0.0017				
Dat 7	0.0	0.0	0.030	0.00074	0.14	0.00073	0.26	0.0014				
TWA^2	0.040	0.0011	0.080	0.0020	0.45	0.0023	0.68	0.0035				
			Amortization	Nalues for Estima	ting Risk 3							
(X/365)* (50/70) 1 use/yr	2.7 x 10 ⁻⁸	2.7 x 10 ⁻⁸		5.0 x 10 ⁻⁸		1.2 x 10 ⁻⁷		1.8 x 10 ⁻⁷				
(70/365)* (50/70) 4 uses/yr	NA		NA		4.6 x 1	4.6 x 10 ⁻⁷		10 ⁻⁷				

Table 12 Continu	Table 12 Continued: Adult Post-Application Exposures-Carcinogenic Assessment of Residential Uses of Tetrachlorvinphos									
Days After Treatment (DAT) ¹	Absorbed Dermal Dose by Scenario ^a (mg/kg/day)									
		Aerosol	Spray			Pump	Spray			
	Α	verage	M	aximum	Av	rerage	N	I aximum		
	%	Dose	%	Dose	%	Dose	%	Dose		
Day 0	2.9	0.021	6.2	0.046	4.7	0.024	6.9	0.036		
Day 1	0.12	0.00089	0.19	0.0014	2.4	0.012	3.8	0.020		
Day 2	0.095	0.00070	0.16	0.0012	1.6	0.0083	2.5	0.013		
Day 3	0.070	0.00052	0.13	0.0010	0.82	0.0043	1.2	0.0062		
Day 4	0.058	0.00043	0.11	0.00081	0.66	0.0034	0.95	0.0049		
Day 5	0.046	0.00034	0.080	0.00059	0.50	0.0026	0.74	0.0038		
Day 6	0.034	0.00025	0.055	0.00041	0.34	0.0018	0.53	0.0028		
Dat 7	0.019	0.00014	0.029	0.00021	0.19	0.0010	0.34	0.0018		
TWA^2	0.42	0.0031	0.87	0.0064	1.4	0.0073	2.1	0.011		
			Amortization	n Values for Estimating Risk	χ ³					
(X/365)* (50/70) 2 uses/yr	1.5 x 10 ⁻⁷		3.2 x 10 ⁻⁷		3.6 x 10 ⁻⁷		5.5 x 10 ⁻⁷			
(Y/365)* (50/70)	7.7 x 10 ⁻⁷		1.6 x 10 ⁻⁶		1.8 x 10 ⁻⁶		2.8 x 10 ⁻⁶			

Note: Collar scenarios were not estimated.

X = (Lower number of uses per year per Table 10) x 7 days postapplication, [Dip X = 1, all others X = (2 uses)]

[Dip Y = 1, Aerosol and pump spray Y = 10, Powder Y = 8]

- DAT (day after treatment) transfer rates of residues from postapplication studies MRIDs 448594-06,-07,-08,-09. Actual data from studies used, and non-collected days (DAT 2, DAT 4-6) interpolated linearly from collected data.
- a The absorbed dermal dose (Day 0-7) = [application rate (in mg)] (TR/100) (0.0957) / (70 kg)The assumptions for application rate were taken from Table 8: Transfer rates were obtained from postapplication studies.
- 2 Time Weighted Average is the average of the transfer rates and the daily doses.
- Risk = $(TWA)(Q_1^*)$. Where $Q_1^* = 0.00183$ (amortization). The amortization is x/365 which considers 7 days of postapplication exposure for minimum treatment from Table 10, and Y/365 which considers

Y = (maximum uses per year per Table 10) x 7 days postapplication exposure.

7 days of post-application exposure for each of the maximum treatments in Table 10. The 50/70 as used in the application scenario are also used for post-application scenarios; this represent years exposed over a 70 year lifetime.

		Average		Maximum			
Scenario	Handler Risk ^a	Postapplication Risk ^b	Total Risk ^c	Handler Risk ^a	Postapplication Risk ^b	Total Risk ^c	
(1)Dip Residential SOPS 4 gallons	3.6 x 10 ⁻⁶	2.7 x 10 ⁻⁸	3.6 x 10 ⁻⁶	3.6 x 10 ⁻⁶	5.0 x 10 ⁻⁸	3.7 x 10 ⁻⁶	
(2)Dip MRID 44859403 + E-FAST; (4 gallons)	3.3 x 10 ⁻⁷	2.7 x 10 ⁻⁸	3.5 x 10 ⁻⁷	3.5 x 10 ⁻⁷	5.0 x 10 ⁻⁸	3.6 x 10 ⁻⁷	
Powder	1.5 x 10 ⁻⁶	1.2 x 10 ⁻⁷	1.6 x 10 ⁻⁶	1.5 x 10 ⁻⁶	1.8 x 10 ⁻⁷	1.6 x 10 ⁻⁶	
Aerosol can	8.6 x 10 ⁻⁹	1.5 x 10 ⁻⁷	1.6 x 10 ⁻⁷	9.3 x 10 ⁻⁹	3.2 x 10 ⁻⁷	3.3 x 10 ⁻⁷	
Pump spray	6.0 x 10 ⁻⁹	3.7 x 10 ⁻⁷	3.8 x 10 ⁻⁷	6.3 x 10 ⁻⁹	5.5 x 10 ⁻⁷	5.6 x 10 ⁻⁷	
•	Combined Application	n and Postapplication Carcinogenic	Risk Assuming Application	s Dip or Powder or Pump Spra	ay with use of a flea collar		
		Average			Maximum		
Scenario	Handler Risk ^a	Post-Application Risk ^b TWA*(35/365)(40/70)	Total Risk	Handler Risk ^a	Post-Application Risk ^b TWA*(35/365)(40/70)	Total Risk	
(1)Dip 4 gallons; SOPS (1x/yr)	3.6 x 10 ⁻⁶	2.5 x 10 ⁻⁸	3.6 x 10 ⁻⁶ 1.0 x 10 ⁻⁷	3.6 x 10 ⁻⁶	5.0 x 10 ⁻⁸	3.7 x 10 ⁻⁶ 1.4 x 10 ⁻⁷	
and Flea Collar (2x/yr)	1.0 x 10 ⁻⁷	- T	3.7 x 10 ⁻⁶	1.4 x 10 ⁻⁷	· [3.8 x 10 ⁻⁶	
(2)Dip (4 gallons:MRID44859403)	3.3 x 10 ⁻⁷	2.5 x 10 ⁻⁸	3.6 x 10 ⁻⁷ 1.0 x 10 ⁻⁷	3.5 x 10 ⁻⁷	5.0 x 10 ⁻⁸	4.0 x 10 ⁻⁷ 1.4 x 10 ⁻⁷	
and Flea Collar (2x/yr)	1.0 x 10 ⁻⁷		4.6 x 10 ⁻⁷	1.4 x 10 ⁻⁷		5.4 x 10 ⁻⁷	
Aerosol and	8.6 x 10 ⁻⁹	1.5 x 10 ⁻⁷	1.6 x 10 ⁻⁷ 1.0 x 10 ⁻⁷	3.8 x 10 ⁻⁸	3.2 x 10 ⁻⁷	3.6 x 10 ⁻⁷ 1.4 x 10 ⁻⁷	
Collar (2x/yr)	1.0×10^{-7}	-	2.6 x 10 ⁻⁷	1.4 x 10 ⁻⁷	-	5.0 x 10 ⁻⁷	
Spray pump	6.0 x 10 ⁻⁹	1.8 x 10 ⁻⁷	1.9 x 10 ⁻⁷	6.3 x 10 ⁻⁹	5.5 x 10 ⁻⁷	5.6 x 10 ⁻⁷	

Table 13: Handler and Postapplication Residential Adult Handler Combined Carcinogenic Risk.								
Average Maximum								
Scenario	Handler Risk ^a	Postapplication Risk ^b	Total Risk ^c	Handler Risk ^a	Postapplication Risk ^b	Total Risk ^c		
			2.9 x 10 ⁻⁶			7.0 x 10 ⁻⁷		

- Values are from Table 10 represent low use per year, 1 dip/year, 2 uses/yr of other products.

 Values are from Table 12: Handler (1/365) = Post-application(7/365); handler (2/365) = postapplication(14/365).

 Total Risk (unitless) = Handler Risk + Postapplication Risk. b